



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Mr. Ashvin Desai  
Manager, Regulatory Affairs  
Prosurg, Inc.  
2195 Trade Zone Blvd.  
SAN JOSE CA 95131

SEP 11 2012

Re: K120766  
Trade/Device Name: NeoScope™ Digital Video Endoscopic System  
Regulation Number: 21 CFR§ 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: FAJ  
Dated: August 27, 2012  
Received: September 4, 2012

Dear Mr. Desai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including; but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

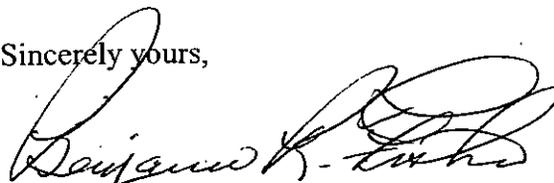
Page 2 -

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,  
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): ~~#~~ K120766

Device Name: **NeoScope™ Digital Video Endoscopic System**

Indications For Use:

The Prosurg's NeoScope (Cystourethroscope /Cystoureteroscope /Cystonephroscope) Digital Video System (which includes the Digital video Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Urinary tract, and can be percutaneously to examine the interior of the kidney and using additional accessories can be used to perform various diagnostic and therapeutic procedures.

The Prosurg's Neoscope (Hysteroscope) Digital Video System (which includes the Digital Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Gynecological tract, and can be percutaneously to examine the interior of the uterus and using additional accessories can be used to perform various diagnostic and therapeutic procedures.

Prescription Use    
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_   
 (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)   
 Division of Reproductive, Gastro-Renal, and   
 Urological Devices

510(k) Number K120766

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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

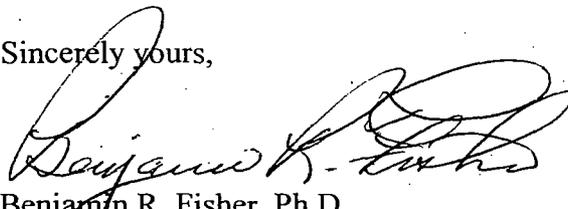
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Sincerely yours,



Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,  
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K120766

Device Name: **NeoScope™- Digital Video Endoscopic System**

Indications For Use:

The Prosurg's NeoScope (Cystourethroscope /Cystoureteroscope /Cystonephroscope) Digital Video System (which includes the Digital video Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Urinary tract, and can be percutaneously to examine the interior of the kidney and using additional accessories can be used to perform various diagnostic and therapeutic procedures.

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Prescription Use  AND/OR Over-The-Counter Use   
(Part 21 CFR.801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Handwritten Signature]*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Gastro-Renal, and  
Urological Devices  
510(k) Number K120766

Page 1 of 1

\* \* \* COMMUNICATION RESULT REPORT ( SEP. 12. 2012 3:54PM ) \* \* \*

FAX HEADER 1:  
FAX HEADER 2:

TRANSMITTED/STORED F. MODE	SEP. 12. 2012 3:48PM OPTION	ADDRESS	RESULT	PAGE
9200 MEMORY TX		4089451390	OK	3/3

REASON FOR ERROR  
E-1) HANG UP OR LINE FAIL  
E-3) NO ANSWERE-2) BUSY  
E-4) NO FACSIMILE CONNECTION

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**COVER SHEET MEMORANDUM**

**From:** Reviewer Name Mary Ed Bueh, R. W. Men  
**Subject:** 510(k) Number K120766/52  
**To:** The Record

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

**Not Substantially Equivalent (NSE) Codes**

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NU NSE for new intended use AND new technology raising new questions of safety and effectiveness
- NP NSE for lack of performance data
- NS NSE no response
- NL NSE for lack of performance data AND no response
- NM NSE pre-amendment device call for PMAs (515i)
- NC NSE post-amendment device requires PMAs
- NH NSE for new molecular entity requires PMA
- TR NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary / 510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?			<input checked="" type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision		<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this a combination product? (Please specify category <u>N</u> , see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			<input checked="" type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?			<input checked="" type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			<input checked="" type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)?			<input checked="" type="checkbox"/>
For United States-based clinical studies only: Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was			<input checked="" type="checkbox"/>

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age <= 21

Neonate/Newborn (Birth to 28 days)

Infant (29 days - < 2 years old)

Child (2 years - < 12 years old)

Adolescent (12 years - < 18 years old)

Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>) Contact OC.

✓  
✓  
✓  
✓  
✓  
✓  
✓  
✓

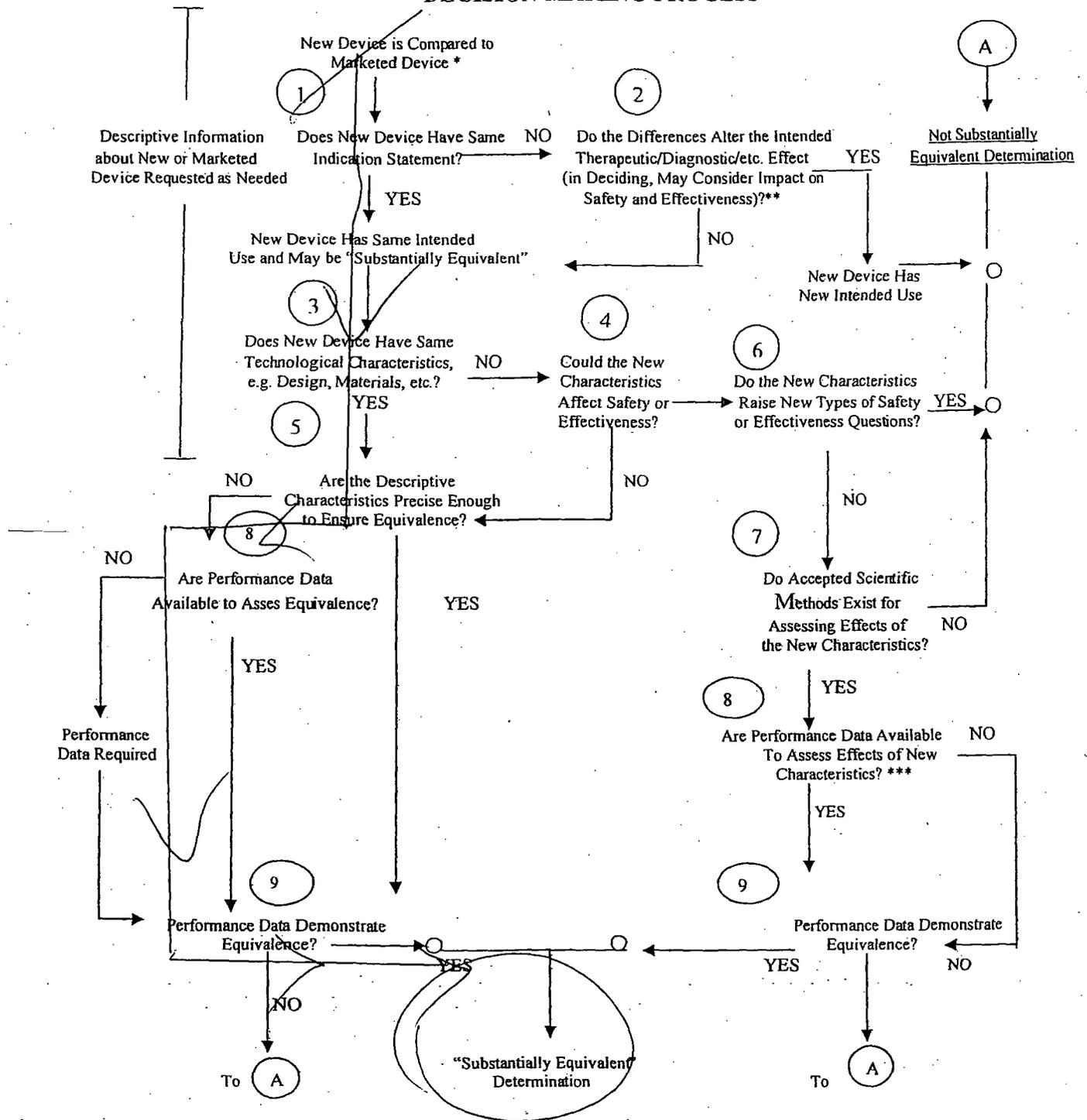
Regulation Number	Class*	Product Code
876-1500	II	FAJ
(*If unclassified, see 510(k) Staff)		

Additional Product Codes:

Review: James P. [Signature] ACTINB/C UDB 9/11/12  
 (Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 9/11/12  
 (Division Director) (Date)

### 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



\* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

\*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

\*\*\* Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.



DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional

K120766/S2

Date: September 11, 2012
To: The Record
From: Mary E. O'Brien, RN, MSN

Office: CDRH/ODE
Division: DRGUD/ULDB

510(k) Holder: Prosurg, Inc.
Device Name: Endoscopic Diagnostic & Treatment System (modification)
Contact: A. Desai
Phone: 408-945-4044
Fax: 408-945-1300
Email: Ashvin@Prosurg.com

I. Purpose and Submission Summary

The 510(k), Prosurg, Inc., holder would like to introduce the Endoscopic Diagnostic & Treatment System (modification) into interstate commerce.

Review Team:

Lead Reviewer: Mary Beth O'Brien, RN, MSN, ULDB
Engineer: Tuan Nguyen, Ph.D., Engineer, ULDB

II. Administrative Requirements

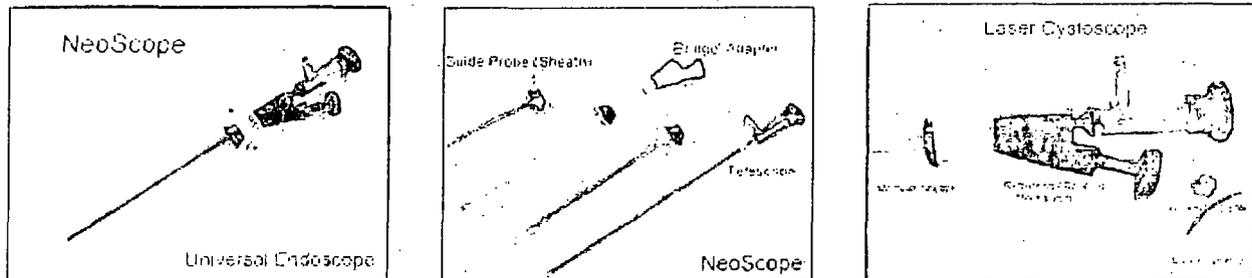
Table with 4 columns: Requirement, Page Reference, Yes, No, N/A. Rows include Indications for Use page, Truthful and Accuracy Statement, 510(k) Summary or 510(k) Statement, and Standards Form.

III. Device Description

Table with 4 columns: Question, Yes, No, N/A. Rows include 'Is the device life-supporting or life sustaining?' and 'Is the device an implant (implanted longer than 30 days)?'

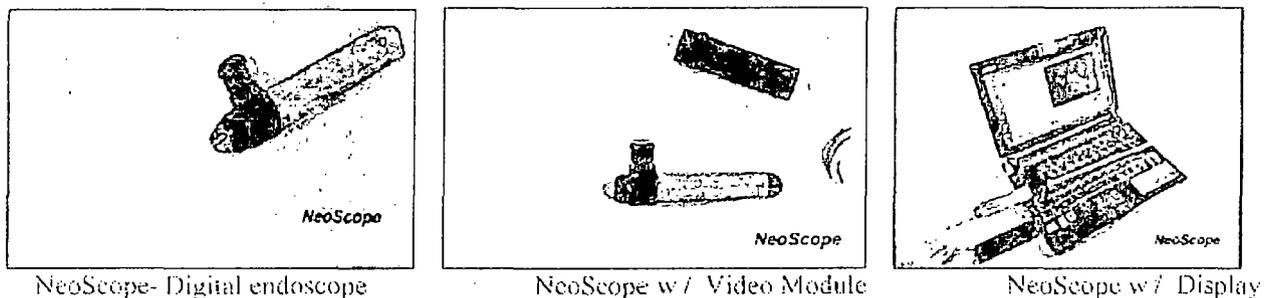
	Yes	No	N/A
Does the device design use software?		✓	
Is the device sterile?	✓		
Is the device reusable (not reprocessed single use)?		✓	
Are "cleaning" instructions included for the end user?			

The NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) is a sterile, single-use modular device for endoscopic diagnostic and treatment. It is compatible with standard endoscopes and interchangeable accessories. The device consists of an outer guide probe, adapter, delivery system and a viewing scope. The outer guide probe is used for irrigation. The delivery system comprises the injection needle and probes for delivering treatment substance, tissue agents, imaging dyes and contrast agents, drugs, sclerosing agents and bio-toxins. It can also be used for delivering thermal energy for tissue ablation and removal using radio frequency (RF), laser, microwave energy, cryo energy. The device can be used in a variety of endoscopic functions such as cystoscope, resectoscope, nephroscope, hysteroscope, and laparoscope. The original NeoScope™ Endoscopic Diagnostic & Treatment System is shown in the following figure.



**Figure 1: The NeoScope™ Endoscopic Diagnostic & Treatment System**

The new NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) consists of a digital viewing endoscope with a LED light source and video module interface for display using commercially available monitoring devices. The new NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) with the proposed modification system is illustrated in the following figure.



**Figure 1: The NeoScope™ Endoscopic Diagnostic & Treatment System (Modification)**

The subject device is designed for optimal visualization via digital imaging technology and to allow fluid irrigation and microsurgical instrument access. It can be introduced through various body cavities and opening.

The following table summarizes the product specifications of the NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) along with their functions and descriptions.

**TABLE 2 – PRODUCT SPECIFICATIONS**

<b>Component/ Function</b>	<b>Description/Model</b>	<b>Material</b>
<b>Outer Guide Probe (Sheath)</b>	Diameter: 10 – 36 Fr Working Length: 10 – 45 cm	Probe: Stainless Steel 304/306 Handle: ABS Probe Tip: Silicon
<b>Delivery System</b>	Diameter: 3 – 10 Fr Working Length: 10 – 45 cm	Injection Needle: Stainless Steel 304/306 RF Electrodes: Stainless Steel 304/306 Catheters: Polyurethane RF Electrode Insulation: TPE/FEP Hub Connector: Polycarbonate Monopolar/Bipolar: Stainless Steel 304/306
<b>Conventional Viewing Endoscope</b>	Diameter: 1.0 – 12 mm Viewing Angle: 0°, 12°, 30°	Outer Tubing: Stainless Steel 304/306 Rod Lens Optics: Quartz
<b>Digital Endoscope (Rigid)</b>	Diameter: 5.0, 7.0, 10.0 mm Working Length: 15, 30, 40 cm Working Channel: 1, 1.5 mm	Rigid Outer Sheath: Stainless Steel 316 Optical Window: Quartz Handle: ABS
<b>Digital Endoscope (Flexible)</b>	Diameter: 5.0, 7.0, 10.0 mm Working Length: 30, 40, 70 cm Working Channel: 1, 1.5 mm	Flexible Outer Sheath: TFE Optical Window: Quartz Handle: ABS
<b>Accessories</b>	Video Interface Module Connecting Cable Video Display Monitor	El Gato video module (Window/Mac OS) USB 2.0 Connector Laptop/Table Computer/Mobile Phone
<b>Packaging</b>	Blister Tray Tyvek Lid Package	Commercially Available

**FDA Concern:**

Please provide a more detailed description of the device and its various configurations, including:  
**(i) Identification and description of each component/accessory, including complete details regarding the thermal energy for tissue ablation and removal using RF (Monopolar I Bipolar), Laser, Microwave energy, Cryo energy and Microsurgical instrumentation), and**  
**(ii) A complete list of all compatible endoscope designs (currently listed as “Storz, Wolf, Circon/Gyrus/ACMI, Olympus & others,” which is open-ended).**

**Sponsor Response:**

The NeoScope Video Endoscopic System consists of three main components:

- (a) Digital Video Endoscope (ProSurg Inc)
- (b) Video Module & Software (El Gato Company)

K120766

ProSurg Endoscope

(c) Laptop I Tablet Computer (Mac, Windows Computer Companies)

Digital Video Endoscope (Rigid /Flexible)

The Digital Video endoscope design incorporates a CMOS imaging sensor and 4 ea built- in LED (Light Emitting Diodes) mounted at the distal end, connecting wires along the length of e hollow tubular structure and a USB 2.0 Connector at the proximal end. The distal end of the endoscope containing CMOS sensor and LEDs, is protected by sealed optical glass window and the proximal end of the tubular structure is housed into a medical grade ABS molded handle. The Neoscope endoscope is provided sterile for Single use only and does not require cleaning, reprocessing or re-sterilization. The Neoscope Endoscope is available as a 5.0 mm OD diagnostic device or 7.5mm OD as an operating device with 5 Fr working channel. The Neoscope can be utilized as a Cystoscope or Hysteroscope by a trained physician for diagnostic and operating procedures, using commercially available, video capture module and portable laptop I Tablet computer.

The Digital Video Endoscopes are supplied sterile for single use only and does not require cleaning, reprocessing or re-sterilization.

Video Capture Module & Software:

The commercially available, Video Capture Module and Video Processing Software, commonly used to convert Analog video (VCR) tapes & other media into Digital files or DVD are supplied by (b)(4) company for use with majority of commercial computers. The Video Capture module with software are not patient contact items and can easily be connected I loaded to the Laptop/ Tablet computer. The Video Capture Module receives the analog signal from CMOS sensor of the endoscope and coverts it into digital video signal recordings. The (b)(4) software is used to format the digital video recordings into commonly used video format files, including Quick Time, i Tune, i Movie, window Media & You Tube.

• Note: The Video module and software are commercially available products ((b)(4) Company) and are non patient contact items. (Supplied non sterile).

Portable Laptop I Tablet Computers:

The Portable Laptop I Tablet Computer can be used as a video monitor and recording I storage device to view, record, edit, store and transfer /transmit the video files. The Digital Video Endoscope and Video Capture Module can be connected to majority of commercially available Laptop /Tablet computer using standard USB 2.0 connecting cables. If necessary, additional USB connecting cable can also be used.

• Note: The Laptop I Tablet Computer is commercially available product (Mac or Windows based Operating System). (Not supplied by ProSurg, Inc.).

(1a) Components and accessories (clarification)

The proposed 510(k) application is only for NeoScope- Digital Video Endoscope System and does not include any micro instruments, RF probes, Laser Fiberoptics, Microwave or Cryo energy delivery devices or other accessories to be supplied by ProSurg, Inc.

The working channel provided in the video endoscope is for suction and irrigation of fluids, commonly used during endoscopic procedures. The working channel can also be used to insert commercially available micro instruments and accessories (max size 5.0 Fr).

K120766

ProSurg Endoscope

4

(1b) The NeoScope – Digital Endoscope device is compatible with commercially available rigid/flexible cystoscope and hysteroscope components, instruments and accessories marketed by Storz, Wolf, Olympus, Circon, ACMI, and Gyrus. The NeoScope can also be used with commercially available suction and irrigation systems for endoscopic use.

NeoScope -Digital Video Cystoscopes & Hysteroscopes (Rigid I Flexible)

Model #	Description	Dimensions
NCR50S	Diagnostic Neo-Cystoscope	5.0 mm Dia, 28 cm length
NCR75S	Operating Neo-Cystoscope	7.5 mm Dia, 28 cm length
NHR50S	Diagnostic Neo-Hysteroscope	5.0 mm Dia, 28 cm length
NHR75S	Operating Neo-Hysteroscope	7.5 mm Dia, 28 cm length
NCF75S	Operating NeoFlex-Cystoscope	7.5 mm Dia, 36 cm length
NHF75S	Operating NeoFlex-Hysteroscope	7.5 mm Dia, 36 cm length
NVMM	Video Module & Software (Mac)	
VMW	Video Module & Software (Windows)	
USB60	USB 2.0 Connecting cable 6.0 ft	
USB12	USB 2.0 Connecting cable 12.0 ft	

*FDA Response:*

*The sponsor has provided more details as to the description of their device and has limited their device to GU and OB/GYN indications. This response is adequate.*

**IV. Indications for Use**

The NeoScope™ Endoscopic Diagnostic & Treatment System (modification) is intended for cystoscopic, hysteroscopic, laparoscopic, resectoscopic and endoscopic treatment of urological, gynecological, gastroenterological disorders and diseases of prostate, bladder, urethra, uterine cavity, stomach, GI, urinary tract and reproductive organs using biomaterials, laser and RF devices, tissue ablatives and augmenting agents, microsurgical instruments and endoscopic accessories

**FDA Concern:**

**You state that the NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) is a newly modified device with cross-specialty applications and therefore subject to the provisions of the Act for premarket notification. The device represents bundled and cross-specialty medical applications. Based on your 510(k) submission, the subject device has applications in many medical subspecialties, encompassing multiple Office of Device Evaluation (ODE) review divisions including urology, ob/gyn and general surgery. This is not consistent with ODE’s bundling policy, according to FDA guidance “Bundling Multiple Devices or Multiple Indications in a Single Submission” (issued 6/22/2007);**

**<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089731.htm>).**

**The urology and gastroenterology device applications can be reviewed by the ODE Branch (Urology and Lithotripsy Devices Branch). However, you should withdraw the general surgical device application (laparoscope) and gynecology (hysteroscope) from this 510(k) and submit them separately for review under a new 510(k) for those review branches.**

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**As indicated in the subsequent deficiencies, the urology and gastroenterology (GU) device applications need to be described in greater detail, with testing, to support their inclusion in this bundled 510(k) submission.**

Sponsor Response:

The sponsor has removed the general surgical device application (laparoscope). This submission included the cystourethroscope, cystoureteroscope, cystonephroscope for GU indications and the hysteroscope for OB/GYN indications. The revised indications for use are the following:

The ProSurg's NeoScope (Cystourethroscope /Cystoureteroscope /Cystonephroscope) Digital Video System (which includes the Digital video Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Urinary tract, and can be percutaneously to examine the interior of the kidney and using additional accessories can be used to perform various diagnostic and therapeutic procedures.

The ProSurg's Neoscope (Hysteroscope) Digital Video System (which includes the Digital Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Gynecological tract, and can be percutaneously to examine the interior of the uterus and using additional accessories can be used to perform various diagnostic and therapeutic procedures.

*FDA Response:*

*The sponsor has change tine indications for use to include only GU and OB/GYN indications. This can be found in K120766/ S1 on the Indications for Use page and in the labeling. This response is adequate.*

#### **V. Predicate Device Comparison**

The sponsor has provided minimal predicate comparison to the subject device.

**FDA Concern:**

**You have provided a limited comparison between your devices and the predicate device to determine substantial equivalence. In order to support the substantial equivalence of your proposed devices and the predicate devices you identify in your 510(k), please provide a detailed tabular comparison of the specifications of your devices and the predicates. For devices with the same intended use as the predicate devices, we would expect to see the comparisons in terms of indications for use, technology, physical dimensions, materials, design and performance specifications including any testing. And, a discussion as to whether those characteristics are the same as the predicates or if they are different, why those differences do not raise new questions of safety and effectiveness and demonstrates that the proposed devices are at least as safe and effective as the legally marketed devices.**

Specifications	Prosurg, Inc. NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) K120766 (subject device)	Prosurg, Inc. NeoScope™ Endoscopic Diagnostic & Treatment System K042780
<b>Indications for Use</b>	<p>(Cystourethroscope /Cystoureteroscope /Cystonephroscope) Digital Video System (which includes the Digital video Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Urinary tract, and can be percutaneously to examine the interior of the kidney and using additional accessories can be used to perform various diagnostic and therapeutic procedures.</p> <p>(Hysteroscope) Digital Video System (which includes the Digital Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Gynecological tract, and can be percutaneously to examine the interior of the uterus and using additional accessories can be used to perform various diagnostic and therapeutic procedures.</p>	Is intended for Cystoscopic, Hysteroscopic, Laparoscopic , Resectoscopic and Endoscopic treatment of Urological, Gynecological, Gastroenterological disorders and diseases of Prostate, Bladder, Urethra, Uterine cavity, Stomach, GI, Urinary tract and Reproductive organs using Biomaterials, Laser & RF devices, Tissue ablative and Augmenting agents, Microsurgical instruments and Endoscopic accessories.
<b>Materials:</b>		
<b>Sheath</b>	Stainless steel / TFE	Stainless steel / TFE
<b>Distal end</b>	Quartz Glass	Quartz Glass
<b>Dimensions:</b>		
<b>Diameter (mm)</b>	5.0 mm, 7.5 mm,	1.0 mm – 12.0 mm
<b>Length (cm)</b>	28 cm – 36 cm	10 cm – 45 cm
<b>Viewing Angle</b>	0 & 30°	0, 12, & 30°
<b>Use</b>	Single use	Reusable
<b>Sterility</b>	Supplied sterile	Supplied sterile

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*FDA Response:*

*This response is adequate.*

## **VI. Labeling**

The sponsor has provided minimal labeling for the subject device.

### **FDA Concern:**

**You should include instructions for use in addition to the labeling provided which addresses:**

- a. **The intended use statement should include specific indications for use, clinical setting, a defined target population, etc. In your case you would have to provide separate labeling for each type of endoscope including the accessories you plan to provide.**
- b. **Directions for use should include:**
  - i) **instructions on how to prepare each type of endoscope for patient use;**
  - ii) **how to insert and remove each type of endoscope;**
  - iii) **other specific physician labeling as to the principles of operation for each type of endoscope and accessories for each type of endoscope you plan to provide;**
  - iv) **a statement of whether each type of endoscope is intended as single use/disposable or reusable. If endoscope is to be labeled as reusable for the same patient, provide adequate instructions about how to clean and sterilize the endoscope, as well as validation as to anticipated changes in device function secondary to reprocessing (e.g., change in antimicrobial status). Functional test procedures for the endoscope prior to use should also be provided, e.g., optical functioning. A separate reprocessing manual may be required**
  - v) **A separate user's manual may be required for the principles of operation of each type of endoscope including the accessories.**
- c. **Contraindications, precautions, warnings, and adverse effects should be included within the labeling for each type of endoscope including the accessories you plan to provide.**

See also Labeling Requirements, at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm>

Sponsor Response:

The Product labeling along with Instructions for Use has been revised for the proposed, single use, NeoScope Cystoscopes/Hysteroscope for Diagnosis and treatment of Urological disorders and Gynecological disorders. The Instructions for Use also includes revised Indications for use, Contraindications, Precautions, Warnings and potential adverse effects associated with the use of the device.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

*FDA Response:*

*The sponsor has changed the indications for use for the cystoscope and the hysteroscope. The Instructions for Use also includes revised Indications for use, Contraindications, Precautions, Warnings and potential adverse effects associated with the use of the device.*

*This can be found in K120766/S1 on pages 13 to 28. This response is adequate.*

**VII. Sterilization/Shelf Life/Reuse**

1. Sterilant:	YES	NO
<p>a. <b>Sterilization method</b> description (e.g., Steam (moist heat), EO, Radiation):</p> <p>b. <b>Dose</b>, for radiation (e.g., 25 – 50 kGy):</p> <p>c. <b>Sterilant residuals</b> remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the standards that have been, or currently are recognized, "ANSI/AAMI/ISO 10993-7:1995 and 2008 <i>Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals</i>," do not include measurement of ethylene glycol residuals);</p>	Ethylene oxide	
	N/A	
	EO – not > 20 mg per day ECH - not > 12 mg per day ETO gas levels were ≤ 0.3 mg / sample and ≤ 1 mg / sample respectively (5 days post sterilization)	
<p><b>2. A description of the Validation Method for the sterilization cycle (not data):</b> (Full citation of an FDA recognized standard is recommended including date (e.g., ANSI/AAMI/ISO 11135:2007)),</p>	ANSI/AAMI/ISO 11135:2007 and EN 550	
<p><b>3. Sterility assurance level (SAL):</b> (e.g., 10<sup>-6</sup> for all devices (except 10<sup>-3</sup> for devices that contact intact skin))</p>	10 <sup>-6</sup>	
<p><b>4. Is it labeled "Pyrogen Free"?</b></p> <p>If so, a description of the method: (e.g., LAL (<i>Limulus Amebocyte Lysate</i> test))</p>	Not stated	✓
	Limulus amebocyte lysate test	
<p><b>5. A description of the packaging</b> (not including package integrity test data):</p>	Blister Tray & Tyvek Lid Package	

**SHELF LIFE**

The sponsor reports that the shelf life for the device is one year, however, have not provided the reports to support a one year shelf life.

**FDA Concern:**

**You have stated that your shelf life determination is for 1 year for your device however, you have not included the reports to support your 1 year shelf life. Your shelf life should be supported by appropriate bench tests and/or sterilization and packaging validation. Please refer to the "Updated 501(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA available at the following web site:**

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<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm>

Sponsor Response:

The recommended Shelf life of the NeoScope™- Digital Video Endoscope System is one year. The product shelf life was determined as per Accelerated aging techniques, based on the assumptions that the chemical reactions involved in the deterioration of materials follow the Arrhenius reaction rate function. The sterilized products were subjected to environmental conditions & were tested to confirm product performance and packaging integrity specifications. The Shelf life Test Report is attached herewith for your review and approval. Time aging test for 12 month will be initiated out upon completion of first manufacturing production lot.

*FDA Response:*

*The sponsor has provided the following test results in the Shelf Life Report found in K120766/S1:*

**10. Test Results:**

*10.1 Product Visual & Functional Tests:*

*10.1.1 Visual Inspection of Neoscope™- Video Endoscope Products & Pkg*

*Visual Inspection Verified that the Neoscope™- Video Endoscopic System product, components, labels and packages were not damaged.*

*10.1.2 Functional Testing of Neoscope™- Video Endoscope Products & Pkg*

*(a) The functional testing of Neoscope™- Video endoscope products was carried out to confirm that they meet product specifications, including video imaging with connection to Video module & Laptop computer.*

*(b) Neoscope™-Video Endoscopic System passed all of the final product Dimensional and functional testing per QP 1130 & QP .1200.*

*10.1.3 Functional Testing of Neoscope™ Video Endoscope Packaging:*

*(a) Neoscope™- Video Endoscope Tyvek I Mylar pouch packages did not get damaged, melted, deformed, torn or broken during shelf life testing.*

*(b) Tyvek I Mylar pouch Packaging Seal integrity did not get damaged, torn or compromised (peel strength) during shelf life testing.*

*(c) There were no holes, puncture or damage to Tyvek I Mylar pouch package (dye check) during shelf life testing.*

**11.0 RECOMMENDED SHELF LIFE:**

*Based on the result of Accelerated Ageing Test Method (ASTM F 1980: 2002) result, we have determined that Neoscope™-Video Endoscope products have a minimum one (1) year shelf life from*

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

*date of manufacturing. Please note that Product Sterility and Shelf life are in effect as long as the package is not opened or damaged.*

*This response is adequate.*

#### **VIII. Biocompatibility**

➤ **Comment:**

The sponsor reports that materials used to manufacture the subject device are identical to the predicate device and are safe and biocompatible materials that are widely used in the medical industry.

#### **FDA Concern:**

**You have stated that materials used to manufacture the subject device are identical to the predicate device and are safe and biocompatible materials that are widely used in the medical industry. Based on your statement, we cannot determine whether you have conducted biocompatibility testing of your final devices according to ISO 10993 standards. We would expect to see biocompatibility testing for limited contact of less than 24 hours to include but not limited to mucosal irritation or intracutaneous reactivity, cytotoxicity, and sensitization on your final sterilized devices Please note that the manufacturing process, including the sterilization process, can significantly affect the biocompatibility of the final device due to the use of different additives and the formation of various byproducts in manufacturing process.. Please clarify whether you have conducted biocompatibility testing of your final, finished, sterilized device as recommended by FDA blue book memo G95-1 and the ISO 10993-1:2009 standard. Please provide testing reports and standards forms for each testing if the test was conducted according to FDA recognized standards. Alternatively, please provide appropriate justification that your device is comprised of the exact same materials and exposed to the same manufacturing processes as the predicate device. Please refer to the guidance documents titled *Blue Book Memo, G95-1, Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices* which can be found at the following web site <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm>**

#### **Sponsor Response:**

The Biocompatibility Report for the NeoScope Diagnostic and Therapeutic Endoscopic System, as per limited Contact device (less than 24 hours) according to ISO 10993 standards has been attached herewith for your review. Please note that the Biocompatibility report includes Cytotoxicity, study ISO intracutaneous study and ISO maximization and Sensitization study for the Neoscope Diagnostic and Therapeutic Endoscopic System. Please note that the material, packaging manufacturing process, sterilization method & cycle are also identical. The Video module and laptop I Tablet computer being, not patient contact items are provided non sterile.

#### **FDA Response:**

*The sponsor has provided the biocompatibility testing of the Neoscope-Diagnostic & Therapeutic Endoscopic System. The results are summarized in following table, followed with in-depth review of each test. In depth review testing for Cytotoxicity, Irritation/Sensitization, and Maximization Sensitization Study was conducted and documented using the attached review templates that are provided by the Biocompatibility Quality Review program and upon review has met requirements for ISO 10993.*

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

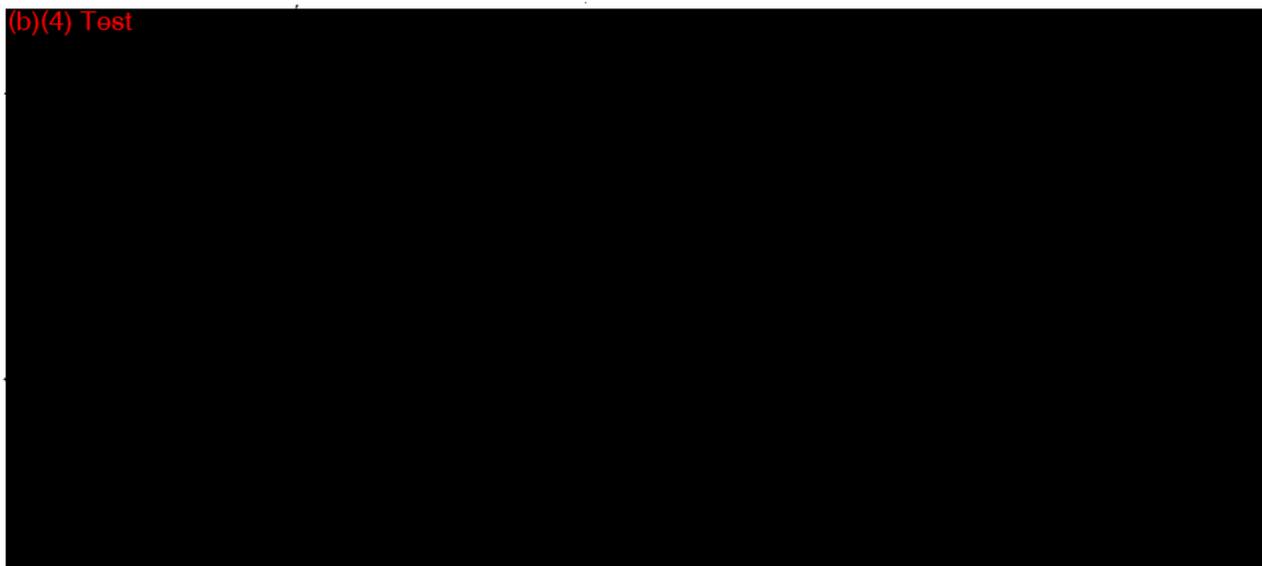


*This response is adequate.*

Standards

In K120766/S1 on page 33 it is reported that FDA Forms 3654 are submitted with this applications, however, these forms were not attached and need to be submitted.

(b)(4) Test



Sponsor Response:

The sponsor has provided the FDA-3654 Standards Data Report for 510(k)'s.

*FDA Response:*

*The sponsor has provided FDA-3654 Standards Data Report for 510(k)'s. These can be found in K120766/S2. This response is adequate.*

**IX. Software**

➤ Comment:

Since the subject device incorporates a digital viewing endoscope with a LED light source and video module interface for display, operating software is needed. The sponsor needs to provide the software evaluation and performance validation according to the following software test requirements.

**Software Test Requirements:**

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices includes the following:

- IEC 62304:2006 Medical Device Software - Software Life Cycle Processes
- <http://www.fda.gov/cdrh/ode/software.html>
- “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf>, 5/11/05
- “Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices”  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073779.pdf>, 9/9/1999
- “General Principles of Software Validation; Final Guidance for Industry and FDA Staff”  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085371.pdf>, 1/11/2002
- “Guidance for Industry. Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software”  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf>, 1/14/05

**FDA Concern:**

**The sponsor needs to address the following software evaluation and performance requirements:**

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

**Level of Concern**

The firm should provide the level of concern, justification and supporting rationale.

**Software Description**

Information should include a summary overview of the features and software operating environment including information on programming language, hardware platform, operating system and off-the-shell software.

**Software Hazard Analysis**

Information should include a tabular description of identified hardware and software hazards, including severity assessment and mitigation(s), clinical hazards, method of control of the hazards and results of evaluating the correct implementation.

**Software Requirements Specifications (SRS)**

Information should include a detailed listing of all of the specific requirements of the software including specifications of the functional requirements for the software in the digital video processor.

**Architecture Design Charts**

Information should include detailed depiction of functional units and software modules; it may also include state diagrams as well as flow charts.

**Software Design Specifications (SDS)**

This information should include a detailed SDS document, which describes how the SRS are implemented.

**Traceability Analysis**

This information should include traceability matrix among requirements, specifications, identified hazards and mitigation(s), including traceability information on risk mitigation measures and implementation of software design specifications, and verification and validation testing.

**Development Plan**

This information should include a summary of the software life cycle development plan, including the configuration management and maintenance plan documents. For a major level of concern, this documentation should also include an annotated list of control documents generated during the development process.

**Verification, Validation, and Testing**

For a minor level of concern, this documentation should include the software functional test plan, pass/fail criteria, and results. For a moderate level of concern, this documentation should include a description of verification and validation (V&V) activities at the unit, integration, and system level, as well as system level test protocol, including pass/fail criteria, and tests results. For a major level of concern, this information should include a description of V&V activities at the unit, integration, and system level as well as unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.

**Revision Level History**

Information should include a revision history log, including release version number and date to document the history of software revisions generated during the development of the software.

**Unresolved Anomalies (Bugs)**

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For moderate and major, the documentation should include a list of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.

**Off-the-Shelf (OTS) Software**

The firm should provide information on any OTS software.

**Cyber and Information Security**

The firm should address security issues associated with network communications since the device may transmit endoscopic images to external servers (such as DICOM servers) via network communications. The firm should also provide information, as appropriate, on the Cybersecurity aspects of their device, including but not limited to, the following facets of information security with respect to communications: confidentiality, integrity, availability and accountability.

Sponsor Response:

Prosurg states that the software for video processing is supplied by El Gato Company, and therefore, software evaluation and performance are not required. However, according to FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, the firm is still responsible for the continued safe and effective performance of their device using off-the-shelf (OTS) software.

(b)(4) Test



*FDA Response:*

*Therefore, the sponsor has adequately addressed this issue.*

**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

➤ Comment:

**Electromagnetic Compatibility**

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

The sponsor has not provided any information on the electromagnetic compatibility of their device to assess its safety and effectiveness.

**FDA Concern:**

**In order to evaluate the electromagnetic compatibility, safety, effectiveness, and reliability of your device according to EMC standard IEC 60601-1-2:2007–Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests – please provide the results of your testing and conclusions for those that are relevant to this standard. Additionally, please provide the following information in order to understand how the testing is performed:**

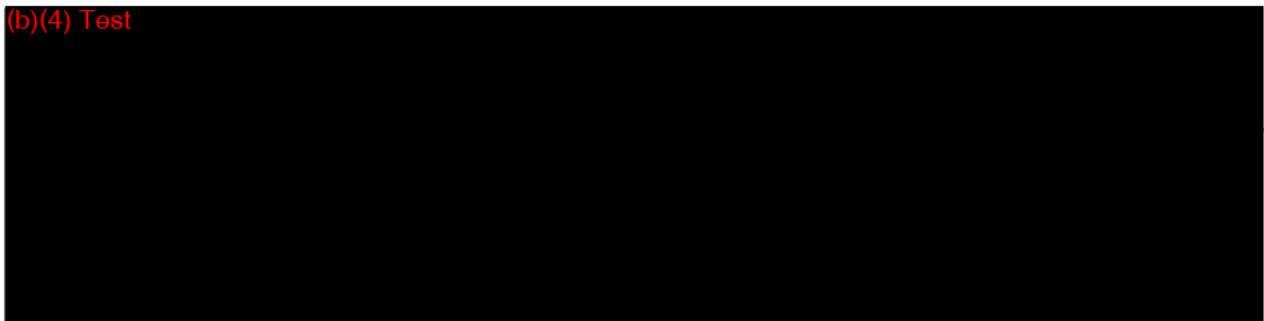
- a. **A summary of the testing that was done;**
- b. **The requirements of the standard that were met (including immunity test levels);**
- c. **The pass/fail criteria used;**
- d. **The functions of the device that were considered to be essential performance;**
- e. **The performance of the device during each immunity test (e.g., degradation observed);**
- f. **Identification and justification for any of the standard 's allowances that were used;**
- g. **A description of and justification for any deviations from the requirements of the standard;**
- h. **Evidence of compliance with the standard' s labeling (identification, marking and documents) requirements;**
- i. **If any device modifications were needed in order to pass any of the EMC testing, a description of these modifications and a statement that they will all be incorporated into the production units.**

**Sponsor Response:**

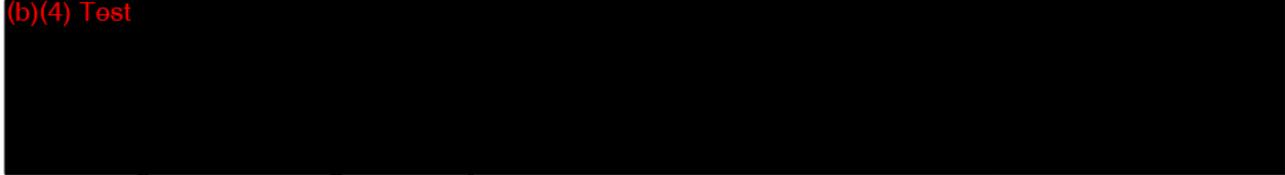
ProSurg states that their devices do not generate electromagnetic radiation and the imaging sensor is supplied by OmniVision. However, they indicate that their digital video endoscope design incorporates CMOS imaging sensor and LED at the distal end. According to EMC standard IEC 60601-1-2:2007–Part 1-2:2007, all electrical medical devices should conform to this consensus standard.

*FDA Response:*

(b)(4) Test



(b)(4) Test



*FDA Response:*

*Therefore, the sponsor has adequately addressed this issue.*

### Electrical Safety

The sponsor did not provide any electrical safety testing to conform to the internationally recognized standards for electrical safety of medical electrical equipment.

### **FDA Concern:**

**You did not provide the electrical safety testing of your device under normal conditions and under the operating conditions which include the use of specified electrical surgical units. In order to ensure that your device is electrically safe according to IEC 60601-1-1:2000 Medical Electrical Equipment – Part 1-1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems and IEC 60601-2-18:1996 + A1:2000 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Endoscopic Equipment – please perform the electrical safety testing of your active device with compatible electro-surgical units and connectors and revise your instructions for use to include compatible electro-surgical units. Please also provide the input parameters of your device that is required to achieve your specified output parameters.**

Sponsor Response:

Prosurg states that their device incorporates the imaging sensor supplied by (b)(4) that meets IEC 60601-1-1:2000 and IEC 60601-2-18:1996&2000. As such they have adequately addressed this issue.

*FDA Response:*

*This response is adequate.*

### Mechanical Safety

The sponsor did not provide any mechanical safety testing of their device to assess its safety and effectiveness.

### **FDA Concern:**

**You did not provide a complete performance testing report summarizing the bench testing of your device and its outcomes, including the number of devices tested or if tests were performed on the final sterilized device. In order to determine the safety and effectiveness of your device please provide a complete report of your product performance testing, including but not limited to the following:**

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

- a. **Leak and pull testing;**
- b. **Handle strength testing.**

Sponsor Response:

ProSurg conducted the performance testing that includes pull force strength, leak, illumination, thermal and functional tests with the accompanying test report. As such they have adequately addressed this issue.

*FDA Response:*

*This can be found in the Test/Evaluation Report: Neoscope™ - Video Endoscope System in K120766/S1. This response is adequate.*

### **Thermal Safety**

The sponsor did not provide any thermal safety testing to conform to the internationally recognized standards for thermal safety of medical electrical equipment.

### **FDA Concern:**

**You did not provide the thermal safety testing of your device. In order to ensure that your device is thermally safe according to IEC 60601-2-18:1996 + A1:2000 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Endoscopic Equipment – please provide the results of your testing and conclusions for the device that applies to this performance standard.**

Sponsor Response:

ProSurg conducted the performance testing that includes pull force strength, leak, illumination, thermal and functional tests with the accompanying test report. As such they have adequately addressed this issue.

*FDA Response:*

*This can be found in the Test/Evaluation Report: Neoscope™ - Video Endoscope System in K120766/S1. This response is adequate.*

### **XI. Performance Testing – Bench**

(b)(4) Test



(b)(4) Test

FDA Response:

This can be found in the Test/Evaluation Report: Neoscope™ - Video Endoscope System in K120766/SI. This response is adequate.

**XII. Performance Testing – Animal**

There are no animal testing requirements for this device.

**XIII. Performance Testing – Clinical**

There are no clinical testing requirements for this device.

**XIV. Substantial Equivalence Discussion**

	Yes	No
1. Same Indication Statement?	✓	If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
3. Same Technological Characteristics?	✓	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		✓ If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?	✓	If NO = Request Data
9. Data Demonstrate Equivalence?	✓	Final Decision: SE

Note: See

[http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_4148/FLOWCHART%20DECISION%20TREE%20.DOC](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC) for Flowchart to assist in decision-making process.

Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

5. Explain how descriptive characteristics are not precise enough:

Standards forms, Software and EMC concerns remain.

9. Data Demonstrated Equivalence:

Standards forms, Software and EMC concerns were adequately addressed.

**XV. Deficiencies**

The sponsor has adequately addressed all the necessary components of the premarket review for a 510(k) submission.

**XVI. Contact History**

**K120766 dated 5 March 2012 received 8 May 2012**

**K120766/S1 10 July 2012 received 18 July 2012**

**K120766/S2 Dated August 27, 2012 received September 4, 2012**

**XVII. Recommendation: SE**

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and accessories

Regulatory Class: Class II

Product Code: FAJ

Mary Ed Bueh Rodman  
Reviewer

9/11/2012

Date

James P. Seiler  
Branch Chief

9/11/2012  
Date



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**MEMORANDUM**

Food and Drug Administration  
Office of Device Evaluation  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

**Engineering Consult**

**K120766/S2**

Date: September 10, 2012  
To: Mary Beth O'Brien  
From: Tuan Nguyen  
CC: Glenn Bell  
510(k) Holder: ProSurg, Inc.  
Device Name: NeoScope™ Endoscopic Diagnostic & Treatment System (Modification)

**I. Purpose and Summary**

Per your request, I have reviewed the sponsor's responses to our AI request in this K120766/S002 submission that was received on August 27, 2012.

The major issues associated with the K120766/S001 consisted of the lack of safety and performance testing including electromagnetic compatibility and software testing. The current review of the K120766/S002 submission evaluates the sponsor's responses to the S1 deficiencies. Based upon the information provided, the sponsor has adequately addressed the deficiencies.

**II. Indications for Use**

The revised Indications-for-Use statements for both the subject device NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) and the predicate NeoScope™ Endoscopic Diagnostic & Treatment System are shown in the following table:

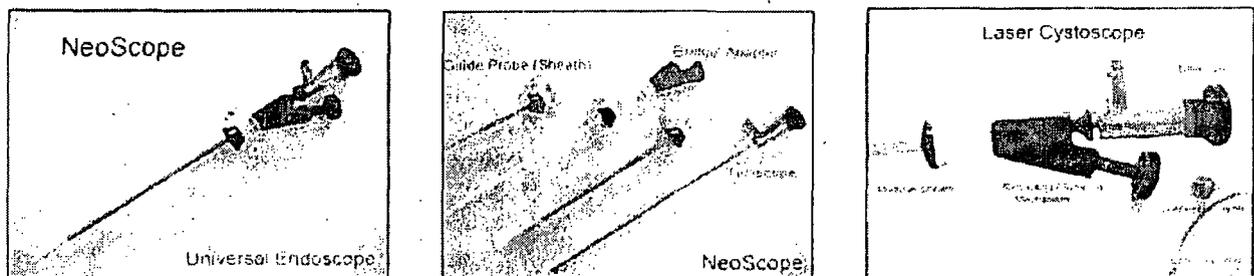
**TABLE 1 – INDICATIONS FOR USE**

Subject Device	Predicate Device
NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) K120766	NeoScope™ Endoscopic Diagnostic & Treatment System K042780

<p><b>Original:</b> The NeoScope™ Endoscopic Diagnostic &amp; Treatment System (Modification) is intended for cystoscopic, hysteroscopic, laparoscopic, resectoscopic and endoscopic treatment of urological, gynecological, gastroenterological disorders and diseases of prostate, bladder, urethra, uterine cavity, stomach, GI, urinary tract and reproductive organs using biomaterials, laser and RF devices, tissue ablative and augmenting agents, microsurgical instruments and endoscopic accessories.</p>	<p><b>Revised:</b> The Prosurg's NeoScope (Cystourethroscope/ Cystonephroscope) Digital Video System (which includes the Digital video Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Urinary tract, and can be percutaneously to examine the interior of the kidney and using additional accessories can be used to perform various diagnostic and therapeutic procedures. The Prosurg's Neoscope (Hysteroscope) Digital Video System (which includes the Digital Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Gynecological tract, and can be percutaneously to examine the interior of the uterus and using additional accessories can be used to perform various diagnostic and therapeutic procedures.</p>	<p>The NeoScope™ Endoscopic Diagnostic &amp; Treatment System is intended for cystoscopic, hysteroscopic, laparoscopic, resectoscopic and endoscopic treatment of urological, gynecological, gastroenterological disorders and diseases of prostate, bladder, urethra, uterine cavity, stomach, GI, urinary tract and reproductive organs using biomaterials, laser and RF devices, tissue ablative and augmenting agents, microsurgical instruments and endoscopic accessories.</p>
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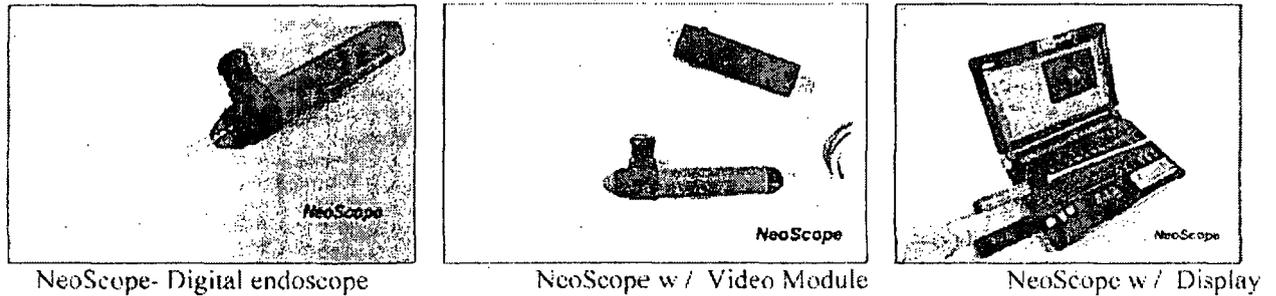
**III. Device Description**

The NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) is a sterile, single-use modular device for endoscopic diagnostic and treatment. It is compatible with standard endoscopes and interchangeable accessories. The device consists of an outer guide probe, adapter, delivery system and a viewing scope. The outer guide probe is used for irrigation. The delivery system comprises the injection needle and probes for delivering treatment substance, tissue agents, imaging dyes and contrast agents, drugs, sclerosing agents and bio-toxins. It can also be used for delivering thermal energy for tissue ablation and removal using radio frequency (RF), laser, microwave energy, cryo energy. The device can be used in a variety of endoscopic functions such as cystoscopy, resectoscopy, nephroscopy, hysteroscopy, and laparoscopy. The original NeoScope™ Endoscopic Diagnostic & Treatment System is shown in the following figure.



**Figure 1: The NeoScope™ Endoscopic Diagnostic & Treatment System**

The new NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) consists of a digital viewing endoscope with a LED light source and video module interface for display using commercially available monitoring devices. The new NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) with the proposed modification system is illustrated in the following figure.



**Figure 1: The NeoScope™ Endoscopic Diagnostic & Treatment System (Modification)**

The subject device is designed for optimal visualization via digital imaging technology and to allow fluid irrigation and microsurgical instrument access. It can be introduced through various body cavities and opening.

The following table summarizes the product specifications of the NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) along with their functions and descriptions.

**TABLE 2 – REVISED PRODUCT SPECIFICATIONS**

Component/ Function	Description/Model	Material
<b>Camera Sensor</b>	CMOS	Commercially Available
<b>Light Source</b>	LED	Commercially Available
<b>Conventional Viewing Endoscope</b>	Diameter: 1.0 mm Viewing Angle: 0°	Outer Tubing: Stainless Steel 304/306 Rod Lens Optics: Quartz
<b>Digital Endoscope (Rigid)</b>	Diameter: 5.0 mm Working Length: 28 cm Working Channel: 1.5 mm	Rigid Outer Sheath: Stainless Steel 316 Optical Window: Quartz Handle: ABS
<b>Digital Endoscope (Flexible)</b>	Diameter: 7.5 mm Working Length: 36 cm Working Channel: 1.5 mm	Flexible Outer Sheath: TFE Optical Window: Quartz Handle: ABS
<b>Accessories</b>	Video Interface Module Connecting Cable Video Display Monitor	Commercially Available
<b>Packaging</b>	Blister Tray Tyvek Lid Package	Commercially Available
<b>Usage</b>	Single Use Only	Supplied Sterile

#### **IV. Device Comparison**

Prosurg provides a revised comparison matrix to include the indications-for-use statement, product specifications, technology, and dimensions along with those of the predicate device. The product specifications are revised and summarized in Table 2 above.

#### **V. Software**

The sponsor states that the software for video processing is supplied by (b)(4) Company and the software installation for the device is not based on private intranet network or public internet (WiFi). As a result, the cyber security risk is low.

#### **VI. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

##### **Electromagnetic Compatibility**

The sponsor states that the digital video endoscope is connected to DC power supply of the computer via USB interface, the imaging sensor does not generate any electromagnetic radiation and the amount of electromagnetic radiation generated by LEDs is low.

##### **Electrical Safety**

Prosurg states that their device incorporates the imaging sensor supplied by (b)(4) that meets IEC 60601-1-1:2000 and IEC 60601-2-18:1996&2000.

##### **Mechanical Safety**

Prosurg conducted the performance testing that includes pull force strength, leak, and illumination, thermal and functional tests with the accompanying test reports.

##### **Thermal Safety**

Prosurg conducted the performance testing that includes pull force strength, leak, and illumination, thermal and functional tests with the accompanying test reports.

#### **VII. Performance Testing – Bench**

##### **Optical Performance**

Prosurg conducted the performance testing that includes pull force strength, leak, and illumination, thermal and functional tests with the accompanying test reports.

#### **VIII. Deficiencies**

##### ***Sponsor Responses to S1 Deficiencies:***

- 1. You state that the software for video processing is supplied by (b)(4) Company, and therefore, software evaluation and performance are not required. We respectfully disagree with your statement. According to FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, you are still responsible for the continued safe and effective performance of their device using off-the-shelf (OTS) software. Please provide information of any OTS software used in your devices following the "Guidance for Industry. Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software."  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf>, 1/14/05**

The sponsor states that the software for video processing is supplied by (b)(4) Company and the software installation for the device is not based on private intranet network or public internet (WiFi). As a result, the cyber security risk is low.

*Therefore, the sponsor has adequately addressed this issue.*

2. You state that your devices do not generate electromagnetic radiation and the imaging sensor is supplied by (b)(4) Test. However, you indicate that your digital video endoscope design incorporates CMOS imaging sensor and LED at the distal end. According to EMC standard IEC 60601-1-2:2007–Part 1-2:2007, all electrical medical devices should conform to this consensus standard. Please provide the electromagnetic compatibility evaluation of your devices to assess their safety and effectiveness in the proximity of other electrical medical devices. Please also provide the results of your testing and conclusions for those that are relevant to this standard.

The sponsor states that the digital video endoscope is connected to DC power supply of the computer via USB interface, the imaging sensor does not generate any electromagnetic radiation and the amount of electromagnetic radiation generated by LEDs is low.

*Therefore, the sponsor has adequately addressed this issue.*

3. You did not provide the risk analysis of your devices. In order to identify the hazards associated with your devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls according to ISO 14971:2007 – Risk Analysis, please provide the results of your risk analysis and conclusions that your devices are safe.

The sponsor states that test data based on laboratory testing demonstrated that their device meets the specifications, is safe and effective for its intended use.

*Therefore, the sponsor has adequately addressed this issue.*

#### **IX. Recommendation**

Based upon the information provided, the sponsor has adequately addressed the deficiencies.



Tuan Nguyen, Ph.D.

The sponsor states that the software for video processing is supplied by (b)(4) Company and the software installation for the device is not based on private intranet network or public internet (WiFi). As a result, the cyber security risk is low.

*Therefore, the sponsor has adequately addressed this issue.*

2. **You state that your devices do not generate electromagnetic radiation and the imaging sensor is supplied by OmniVision. However, you indicate that your digital video endoscope design incorporates CMOS imaging sensor and LED at the distal end. According to EMC standard IEC 60601-1-2:2007–Part 1-2:2007, all electrical medical devices should conform to this consensus standard. Please provide the electromagnetic compatibility evaluation of your devices to assess their safety and effectiveness in the proximity of other electrical medical devices. Please also provide the results of your testing and conclusions for those that are relevant to this standard.**

The sponsor states that the digital video endoscope is connected to DC power supply of the computer via USB interface, the imaging sensor does not generate any electromagnetic radiation and the amount of electromagnetic radiation generated by LEDs is low.

*Therefore, the sponsor has adequately addressed this issue.*

#### **IX. Recommendation**

Based upon the information provided, the sponsor has adequately addressed the deficiencies.



Tuan Nguyen, Ph.D.



U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

September 05, 2012

PROSURG, INC.  
2195 TRADE ZONE BLVD.  
SAN JOSE, CALIFORNIA 95131  
ATTN: A. DESAI

510k Number: K120766

Product: ENDOSCOPIC DIAGNOSTIC &

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

**Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.**

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

K120766/S2



Attn:  
Mary Beth O'Brien, RN, MSN

Aug 27, 2012

Urology and Lithotripsy Devices Branch  
Division of Reproductive, Gastro-Renal & Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

FDA CDRH DMC  
SEP 4 2012  
Received K51

Re: **NeoScope: ( Ref 510K 120766)**

Dear Ms O'brien,

Based on your request , I would like to submit a response to your questions.  
Please review the response and let me know if it meets your approval.

**Electromagnetic Compatibility:**

The digital Video Endoscope consists of CMOS imaging sensor (Omnivision) and Four built-in LEDs mounted at the distal end of the endoscopic device. The digital video endoscope is connected to **DC power supply** of the laptop / tablet computer via USB interface and not to the electrical wall outlet. The nominal output of USB 2.0 of the Laptop / tablet computer is 3.5 - 5.0 volts and current is 250mA- 500mA. Please note that ProSurg does not market or sell any Laptop or Tablet computers and EMC compliance of computer is responsibility of computer manufacturers.

The Imaging sensor is designed to capture the image of the target site and does not generate any Electromagnetic radiation. The power consumption is DC 3.5 -5.0 volts. and 20mA. ( Please refer to attached specifications for CMOS sensor)

The LED module is designed to illuminate the target site and power consumption is only 20 mA. ( please refer to attached specifications for LED)

The amount of Electromagnetic radiation generated by LEDs is extremely low . The low level of Electromagnetic radiation from LED for the proposed device is so low that it is safer than computer and the potential risk to the physician, patients , support personnel and equipments in the clinic or operating room is extremely low.

**Software:**

Based on your recommendation, we reviewed FDA's Guidance Document for Cybersecurity for **Networked Medical** devices containing Off the shelf (OTC) software.

**PROSURG, INC.**

2193 Trade Zone Blvd. San Jose, CA 95131

Tel: (408) 945-4044, 1-800-200-SURG Fax: (408) 945-1390

Questions? Contact FDA/CDRH/CEMID at [CDRH@FDA.hhs.gov](mailto:CDRH@FDA.hhs.gov) or 301-796-8118

The software for video processing is supplied with Video module supplied by (b) (b)(4) Company. Please note that software installation on Mac or Windows based laptop / Tablet computers is using a software installation disc (with key ) and not via Internet or Wi Fi connection. Please note that the software installation for the proposed device is not based on private intranet network or public internet (WI Fi). As a result, the cyber security risk is extremely low, once the software is installed properly by authorized user. It is not possible for unauthorized access to the installed software on user's computer system with password protection.

The Laptop / Tablet computers are not supplied by Prosurg. As a result, the user is responsible to install computer security software on the computer.

Additionally , we can provide Caution statement in the Instructions for Use to install only authorized software for use with Digital Video endoscope to avoid risk of cyber security.

**Standards : ( Attached Forms)**

**IEC 60601-1-2: 2007** - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic Compatibility - Requirements and Tests

**ANSI / ISO 11135-1:** Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization

**AAMI/ANSI /ISO 11607-1-** Packaging for Terminally Sterilized Medical Devices

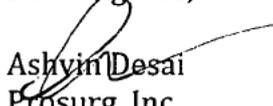
**AAMI/ ANSI/ ISO 10993-1** - Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing

The sterilization validation is based on ANSI/AAMI / ISO 11135-1: 2007 and EN 550: 1994 guidelines for ETO sterilization

The Gas Residual levels for the proposed device, with contact for limited exposure devices, based on ANSI /AAMI /ISO 10993-7: - 2008 – Biological Evaluation of Medical Devices- Part 7 "Ethylene Oxide Sterilization Residuals"

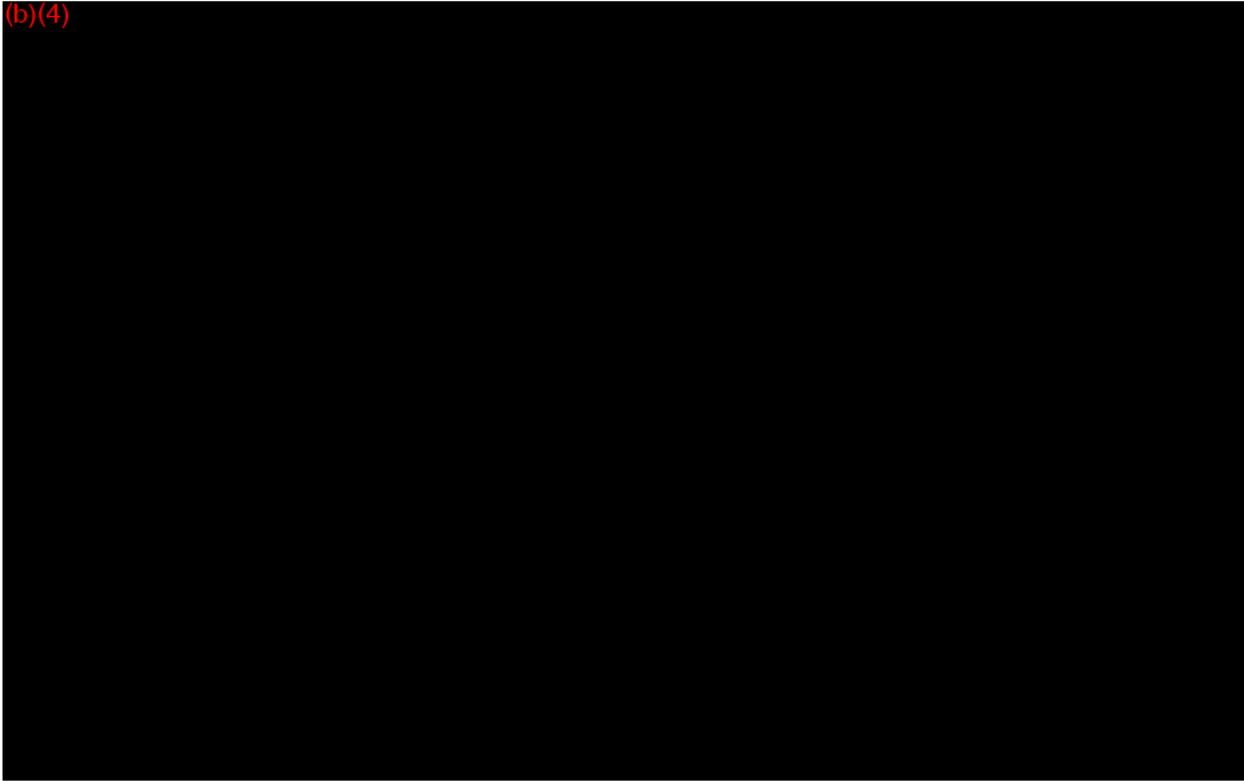
Once again thank you for your cooperation and assistance.

Best Regards,

  
Ashvin Desai  
Prosurg, Inc  
San Jose CA  
Tel 408 483 5474

**Camera / LED Module Specifications:**

(b)(4)



Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup> AAAMI/ANSI/ISO 10993-5  
10993-10 2009  
Biological evaluation of medical devices (Biocompatibility)

Please answer the following questions

Yes No

Is this standard recognized by FDA<sup>2</sup>?  Yes  No

FDA Recognition number<sup>3</sup> # 2-118  
2-153  
2-152

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?  Yes  No

Is a summary report<sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)?  Yes  No  
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?  Yes  No

Does this standard include acceptance criteria?  Yes  No  
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?  Yes  No  
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?  Yes  No  
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)<sup>5</sup>?  Yes  No

Were deviations or adaptations made beyond what is specified in the FDA SIS?  Yes  No  
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?  Yes  No  
If yes, report these exclusions in the summary report table.

Is there an FDA guidance<sup>6</sup> that is associated with this standard?  Yes  No  
If yes, was the guidance document followed in preparation of this 510(k)?  Yes  No

Title of guidance: Biocompatibility - Medical Devices

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

Department of Health and Human Services  
Food and Drug Administration  
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup> ISO - 11607-1: 2006

Packaging for Terminally Sterilized Medical Devices - Part I

Please answer the following questions

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 14-355

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....       
If yes, was the guidance document followed in preparation of this 510(k)? .....    

Title of guidance: sterility - Medical Devices

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

Department of Health and Human Services  
Food and Drug Administration  
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup> ISO 10993-7:2008  
Biological Evaluation of Medical Devices Part 7. ETO Residual

**Please answer the following questions** Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....

FDA Recognition number <sup>3</sup> ..... # 14-278

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....    
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....

Does this standard include acceptance criteria? .....    
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If yes, report these exclusions in the summary report table.

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If yes, was the guidance document followed in preparation of this 510(k)? .....

Title of guidance: Sterility - Medical Devices

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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In the first trial to evaluate which route of delivery optimizes outcomes in women with eclampsia, researchers found that labor induction and cesarean section are associated with

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**Cesarean Delivery in Eclampsia May Not Improve Outcomes**  
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**The Relationship Between Placental Location and Fetal Gender (Ramzi's Method)**  
123 people recommend this.

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Department of Health and Human Services  
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup> ISO 11135-1:2007

Sterilization of Health care products - ETO Part I. Sterilization process control

Please answer the following questions

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 14-331

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....         
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....      

Does this standard include acceptance criteria? .....         
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....         
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....         
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 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....         
 If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: sterility - Medical Devices

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

Department of Health and Human Services  
 Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
 (To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup> *IEC-60601-2*  
*Medical Electrical Equipment*

**Please answer the following questions** Yes    No

Is this standard recognized by FDA <sup>2</sup>?    

FDA Recognition number <sup>3</sup> # *6-233*

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)?       
 If no, complete a summary report table. *Extremely low voltage of LED*

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? *Test not conducted due to low level*    

Does this standard include acceptance criteria?       
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?       
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?       
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>?    

Were deviations or adaptations made beyond what is specified in the FDA SIS?       
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?       
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?       
 If yes, was the guidance document followed in preparation of this 510(k)?    

Title of guidance: *EMC - Electromagnetic compatibility*

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]      address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.  
<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>  
<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>  
<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and  
<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>  
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FAX HEADER 1:  
FAX HEADER 2:

TRANSMITTED/STORED MODE	DATE TIME	OPTION	ADDRESS	RESULT	PAGE
8516 MEMORY TX	AUG. 15. 2012 2:14PM		4089451390	OK	3/3

REASON FOR ERROR  
E-1) HANG UP OR LINE FAIL  
E-3) NO ANSWER

E-2) BUSY  
E-4) NO FACSIMILE CONNECTION



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Mr. Ashvin Desai  
Manager, Regulatory Affairs  
ProSurg, Inc.  
2193 Trade Zone Boulevard  
SAN JOSE CA 95131

AUG 15 2012

Re: K120766  
Trade Name: Endoscopic Diagnostic & Treatment System (Modification)  
Dated: July 10, 2012  
Received: July 18, 2012

Dear Mr. Desai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device because you did not completely respond to the deficiencies listed in our June 25, 2012 letter. To complete the review of your submission, we require the following.

Software

You state that the software for video processing is supplied by (b)(4) Company, and therefore, software evaluation and performance are not required. We respectfully disagree with your statement. According to FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, you are still responsible for the continued safe and effective performance of their device using off-the-shelf (OTS) software. Please provide information of any OTS software used in your devices following the "Guidance for Industry. Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software"  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf>.

Electromagnetic Compatibility

You state that your devices do not generate electromagnetic radiation and the imaging sensor is supplied by OmniVision. However, you indicate that your digital video endoscope design incorporates CMOS imaging sensor and LED at the distal end. According to EMC standard IEC 60601-1-2:2007-Part 1-2:2007, all electrical medical devices should conform to this consensus standard. Please provide the electromagnetic compatibility evaluation of your devices to assess their safety and effectiveness in the proximity of other electrical medical devices. Please also provide the results of your testing and conclusions for those that are relevant to this standard.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

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Manager, Regulatory Affairs  
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## Standards

You have reported that your device is in compliance with several standards. The FDA-3654 Standards Data Report for 510(k)'s was recently made available on FDA's Internet website and should be provided in a 510(k) when a standard is referenced. This is required for all standards referenced in your submission. These forms are available to you in either portable document format (PDF) found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

Please complete this form for each standard cited in your 510(k) submission, for example, as found in Section 10 – Product Testing of your response to our June 25, 2012 additional information letter. This form is used to supply information suggested in the Recognition and Use of Consensus Standards; Final Guidance for Industry under the section entitled, Procedures for the Use of Consensus Standards, found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077274.htm>.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

**If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, “FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment” at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf>. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.**

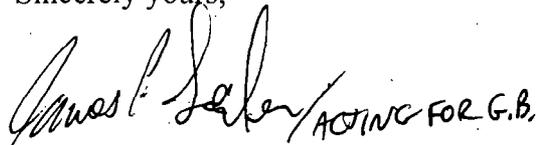
If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter and would like to set up a teleconference, please contact Mary Beth O'Brien, RN, MSN at (301) 796-6557. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100, or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Glenn B. Bell, Ph.D.  
Acting Chief, Urology and Lithotripsy  
Devices Branch  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

**K120766 – ProSurg, Inc.**

cc: DMC - 2 copies  
ODE/DRGUD/ULDB (MOA)

**Drafted:** MOA:8.14.2012  
**Final:** MOA:clr:8.14.2012

Division/Branch	Last Name	Date	Division/Branch	Last Name	Date
DRGUD/ULDB	OBRJEN	8/15/2012			
DRGUD/ULDB	Sefer	8/15/2012			



**COVER SHEET MEMORANDUM**

**From:** Reviewer Name Mary E. Byer, R.D.M.  
**Subject:** 510(k) Number K121076d/S1  
**To:** The Record

Please list CTS decision code AL  
 Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))  
 Hold (Additional Information or Telephone Hold).  
 Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NU NSE for new intended use AND new technology raising new questions of safety and effectiveness
- NP NSE for lack of performance data
- NS NSE no response
- NL NSE for lack of performance data AND no response
- NM NSE pre-amendment device call for PMAs (515i)
- NC NSE post-amendment device requires PMAs
- NH NSE for new molecular entity requires PMA
- TR NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	<i>Attach IFU</i>		
510(k) Summary /510(k) Statement	<i>Attach Summary</i>		
Truthful and Accurate Statement.	<i>Must be present for a Final Decision</i>		
Is the device Class III?			
If yes, does firm include Class III Summary?	<i>Must be present for a Final Decision</i>		
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )			
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies <b>only</b> : Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age <= 21

Neonate/Newborn (Birth to 28 days)

Infant (29 days - < 2 years old)

Child (2 years - < 12 years old)

Adolescent (12 years - < 18 years old)

Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>) Contact OC.

Regulation Number	Class*	Product Code
-------------------	--------	--------------

(\*If unclassified, see 510(k) Staff)

Additional Product Codes: \_\_\_\_\_

Review: \_\_\_\_\_

JAMES SEIBER Acting  
(Branch Chief) for Glenn Bell

VLDB  
(Branch Code)

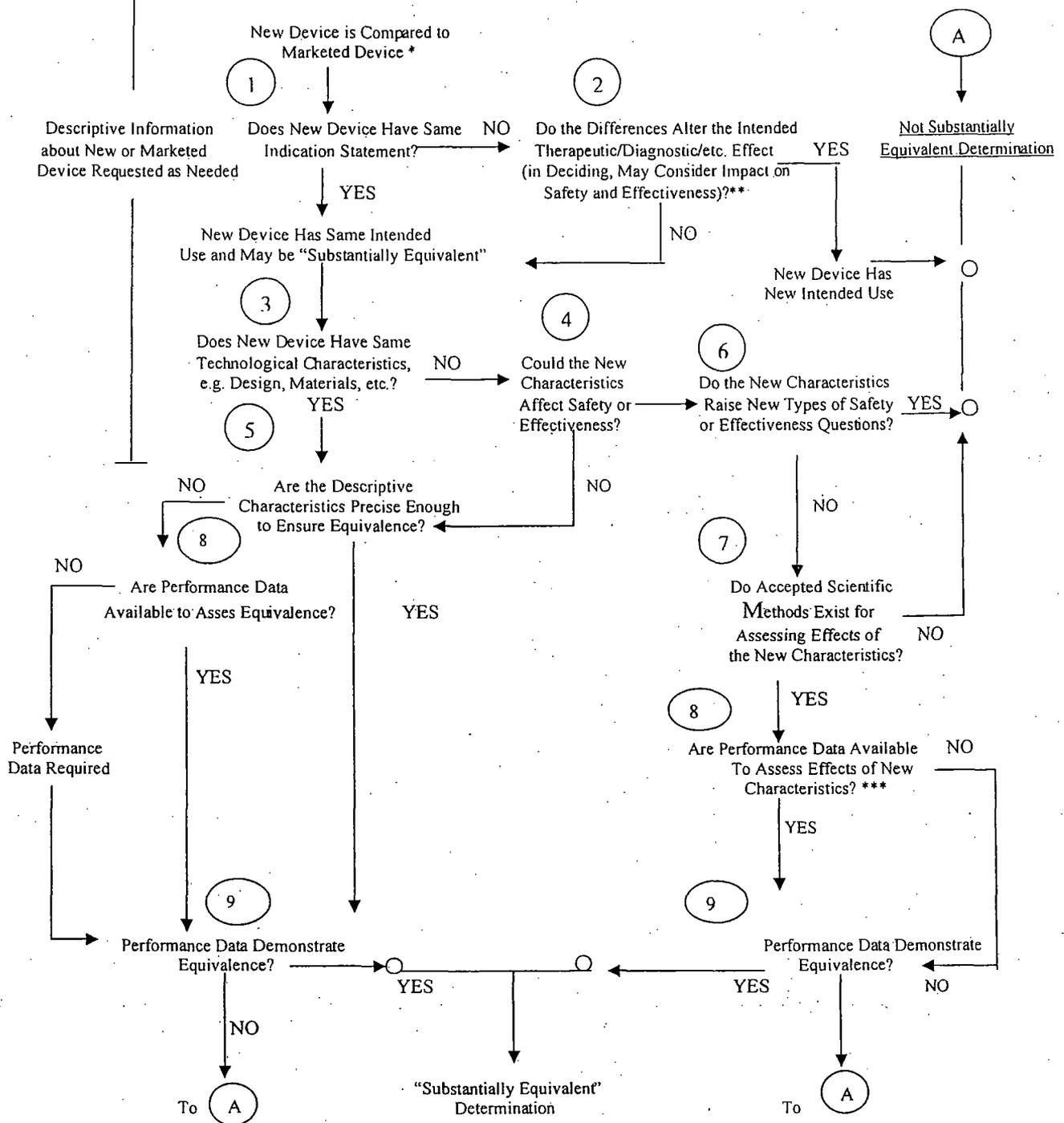
8/15/2012  
(Date)

Final Review: \_\_\_\_\_

(Division Director)

(Date)

### 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



\* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

\*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

\*\*\* Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional

K120766/S1

Date: August 14, 2012
To: The Record
From: Mary E. O'Brien, RN, MSN

Office: CDRH/ODE
Division: DRGUD/ULDB

510(k) Holder: Prosurg, Inc.
Device Name: Endoscopic Diagnostic & Treatment System (modification)
Contact: A. Desai
Phone: 408-945-4044
Fax: 408-945-1300
Email: Ashvin@Prosurg.com

I. Purpose and Submission Summary

The 510(k), Prosurg, Inc., holder would like to introduce the Endoscopic Diagnostic & Treatment System (modification) into interstate commerce.

Review Team:

Lead Reviewer: Mary Beth O'Brien, RN, MSN, ULDB
Engineer: Tuan Nguyen, Ph.D., Engineer, ULDB

II. Administrative Requirements

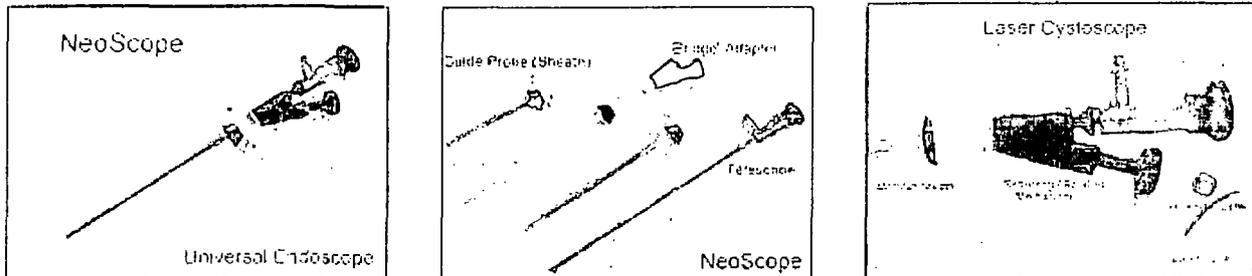
Table with 4 columns: Requirement, Page, Yes, No, N/A. Rows include Indications for Use page, Truthful and Accuracy Statement, 510(k) Summary or 510(k) Statement, and Standards Form.

III. Device Description

Table with 4 columns: Question, Yes, No, N/A. Rows include 'Is the device life-supporting or life sustaining?' and 'Is the device an implant (implanted longer than 30 days)?'

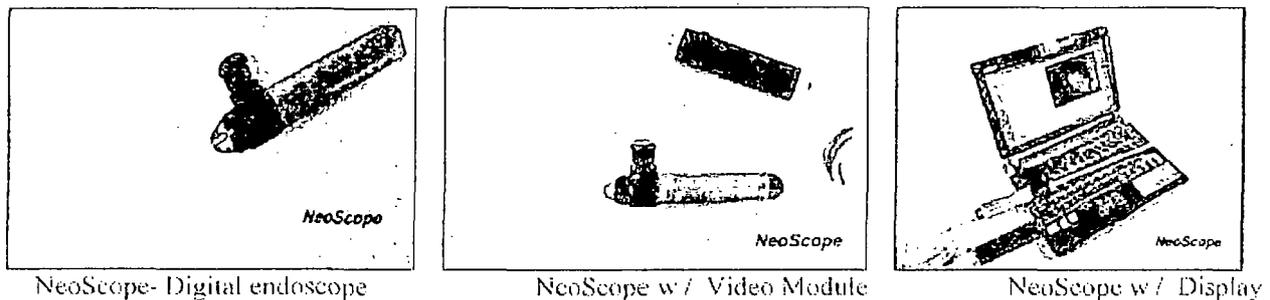
	Yes	No	N/A
Does the device design use software?		✓	
Is the device sterile?	✓		
Is the device reusable (not reprocessed single use)?		✓	
Are "cleaning" instructions included for the end user?			

The NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) is a sterile, single-use modular device for endoscopic diagnostic and treatment. It is compatible with standard endoscopes and interchangeable accessories. The device consists of an outer guide probe, adapter, delivery system and a viewing scope. The outer guide probe is used for irrigation. The delivery system comprises the injection needle and probes for delivering treatment substance, tissue agents, imaging dyes and contrast agents, drugs, sclerosing agents and bio-toxins. It can also be used for delivering thermal energy for tissue ablation and removal using radio frequency (RF), laser, microwave energy, cryo energy. The device can be used in a variety of endoscopic functions such as cystoscope, resectoscope, nephroscope, hysteroscope, and laparoscope. The original NeoScope™ Endoscopic Diagnostic & Treatment System is shown in the following figure.



**Figure 1: The NeoScope™ Endoscopic Diagnostic & Treatment System**

The new NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) consists of a digital viewing endoscope with a LED light source and video module interface for display using commercially available monitoring devices. The new NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) with the proposed modification system is illustrated in the following figure.



**Figure 1: The NeoScope™ Endoscopic Diagnostic & Treatment System (Modification)**

The subject device is designed for optimal visualization via digital imaging technology and to allow fluid irrigation and microsurgical instrument access. It can be introduced through various body cavities and opening.

The following table summarizes the product specifications of the NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) along with their functions and descriptions.

**TABLE 2 – PRODUCT SPECIFICATIONS**

<b>Component/ Function</b>	<b>Description/Model</b>	<b>Material</b>
<b>Outer Guide Probe (Sheath)</b>	Diameter: 10 – 36 Fr Working Length: 10 – 45 cm	Probe: Stainless Steel 304/306 Handle: ABS Probe Tip: Silicon
<b>Delivery System</b>	Diameter: 3 – 10 Fr Working Length: 10 – 45 cm	Injection Needle: Stainless Steel 304/306 RF Electrodes: Stainless Steel 304/306 Catheters: Polyurethane RF Electrode Insulation: TPE/FEP Hub Connector: Polycarbonate Monopolar/Bipolar: Stainless Steel 304/306
<b>Conventional Viewing Endoscope</b>	Diameter: 1.0 – 12 mm Viewing Angle: 0°, 12°, 30°	Outer Tubing: Stainless Steel 304/306 Rod Lens Optics: Quartz
<b>Digital Endoscope (Rigid)</b>	Diameter: 5.0, 7.0, 10.0 mm Working Length: 15, 30, 40 cm Working Channel: 1, 1.5 mm	Rigid Outer Sheath: Stainless Steel 316 Optical Window: Quartz Handle: ABS
<b>Digital Endoscope (Flexible)</b>	Diameter: 5.0, 7.0, 10.0 mm Working Length: 30, 40, 70 cm Working Channel: 1, 1.5 mm	Flexible Outer Sheath: TFE Optical Window: Quartz Handle: ABS
<b>Accessories</b>	Video Interface Module Connecting Cable Video Display Monitor	(b)(4) video module (Window/Mac OS) USB 2.0 Connector Laptop/Table Computer/Mobile Phone
<b>Packaging</b>	Blister Tray Tyvek Lid Package	Commercially Available

**FDA Concern:**

Please provide a more detailed description of the device and its various configurations, including:  
 (i) Identification and description of each component/accessory, including complete details regarding the thermal energy for tissue ablation and removal using RF (Monopolar I Bipolar), Laser, Microwave energy, Cryo energy and Microsurgical instrumentation), and  
 (ii) A complete list of all compatible endoscope designs (currently listed as “Storz, Wolf, Circon/Gyrus/ACMI, Olympus & others,” which is open-ended).

**Sponsor Response:**

The NeoScope Video Endoscopic System consists of three main components:

- (a) Digital Video Endoscope (ProSurg Inc)
- (b) Video Module & Software ((b)(4) Company)

K120766  
ProSurg Endoscope

(c) Laptop I Tablet Computer (Mac, Windows Computer Companies)

Digital Video Endoscope (Rigid /Flexible)

The Digital Video endoscope design incorporates a CMOS imaging sensor and 4 ea built- in LED (Light Emitting Diodes) mounted at the distal end, connecting wires along the length of e hollow tubular structure and a USB 2.0 Connector at the proximal end. The distal end of the endoscope containing CMOS sensor and LEDs, is protected by sealed optical glass window and the proximal end of the tubular structure is housed into a medical grade ABS molded handle. The Neoscope endoscope is provided sterile for Single use only and does not require cleaning, reprocessing or re-sterilization. The Neoscope Endoscope is available as a 5.0 mm OD diagnostic device or 7.5mm OD as an operating device with 5 Fr working channel. The Neoscope can be utilized as a Cystoscope or Hysteroscope by a trained physician for diagnostic and operating procedures, using commercially available, video capture module and portable laptop I Tablet computer.

The Digital Video Endoscopes are supplied sterile for single use only and does not require cleaning, reprocessing or re-sterilization.

Video Capture Module & Software:

The commercially available, Video Capture Module and Video Processing Software, commonly used to convert Analog video (VCR) tapes & other media into Digital files or DVD are supplied by (b)(4) company for use with majority of commercial computers. The Video Capture module with software are not patient contact items and can easily be connected I loaded to the Laptop/ Tablet computer. The Video Capture Module receives the analog signal from CMOS sensor of the endoscope and converts it into digital video signal recordings. The (b)(4) software is used to format the digital video recordings into commonly used video format files, including Quick Time, i Tune, i Movie, window Media & You Tube.

• Note: The Video module and software are commercially available products ((b)(4) Company) and are non patient contact items. (Supplied non sterile).

Portable Laptop I Tablet Computers:

The Portable Laptop I Tablet Computer can be used as a video monitor and recording I storage device to view, record, edit, store and transfer /transmit the video files. The Digital Video Endoscope and Video Capture Module can be connected to majority of commercially available Laptop /Tablet computer using standard USB 2.0 connecting cables. If necessary, additional USB connecting cable can also be used.

• Note: The Laptop I Tablet Computer is commercially available product (Mac or Windows based Operating System). (Not supplied by ProSurg, Inc.).

(1a) Components and accessories (clarification)

The proposed 510(k) application is only for NeoScope- Digital Video Endoscope System and does not include any micro instruments, RF probes, Laser Fiberoptics, Microwave or Cryo energy delivery devices or other accessories to be supplied by ProSurg, Inc.

The working channel provided in the video endoscope is for suction and irrigation of fluids, commonly used during endoscopic procedures. The working channel can also be used to insert commercially available micro instruments and accessories (max size 5.0 Fr).

K120766

ProSurg Endoscope

4

(1b) The NeoScope – Digital Endoscope device is compatible with commercially available rigid/flexible cystoscope and hysteroscope components, instruments and accessories marketed by Storz, Wolf, Olympus, Circon, ACMI, and Gyrus. The NeoScope can also be used with commercially available suction and irrigation systems for endoscopic use.

NeoScope -Digital Video Cystoscopes & Hysteroscopes (Rigid I Flexible)

Model #	Description	Dimensions
NCR50S	Diagnostic Neo-Cystoscope	5.0 mm Dia, 28 cm length
NCR75S	Operating Neo-Cystoscope	7.5 mm Dia, 28 cm length
NHR50S	Diagnostic Neo-Hysteroscope	5.0 mm Dia, 28 cm length
NHR75S	Operating Neo-Hysteroscope	7.5 mm Dia, 28 cm length
NCF75S	Operating NeoFlex-Cystoscope	7.5 mm Dia, 36 cm length
NHF75S	Operating NeoFlex-Hysteroscope	7.5 mm Dia, 36 cm length
NVMM	Video Module & Software (Mac)	
VMW	Video Module & Software (Windows)	
USB60	USB 2.0 Connecting cable 6.0 ft	
USB12	USB 2.0 Connecting cable 12.0 ft	

*FDA Response:*

*The sponsor has provided more details as to the description of their device and has limited their device to GU and OB/GYN indications. This response is adequate.*

**IV. Indications for Use**

The NeoScope™ Endoscopic Diagnostic & Treatment System (modification) is intended for cystoscopic, hysteroscopic, laparoscopic, resectoscopic and endoscopic treatment of urological, gynecological, gastroenterological disorders and diseases of prostate, bladder, urethra, uterine cavity, stomach, GI, urinary tract and reproductive organs using biomaterials, laser and RF devices, tissue ablative and augmenting agents, microsurgical instruments and endoscopic accessories

**FDA Concern:**

**You state that the NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) is a newly modified device with cross-specialty applications and therefore subject to the provisions of the Act for premarket notification. The device represents bundled and cross-specialty medical applications. Based on your 510(k) submission, the subject device has applications in many medical subspecialties, encompassing multiple Office of Device Evaluation (ODE) review divisions including urology, ob/gyn and general surgery. This is not consistent with ODE’s bundling policy, according to FDA guidance “Bundling Multiple Devices or Multiple Indications in a Single Submission” (issued 6/22/2007);**

**<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089731.htm>**).

**The urology and gastroenterology device applications can be reviewed by the ODE Branch (Urology and Lithotripsy Devices Branch). However, you should withdraw the general surgical device application (laparoscope) and gynecology (hysteroscope) from this 510(k) and submit them separately for review under a new 510(k) for those review branches.**

**As indicated in the subsequent deficiencies, the urology and gastroenterology (GU) device applications need to be described in greater detail, with testing, to support their inclusion in this bundled 510(k) submission.**

**Sponsor Response:**

The sponsor has removed the general surgical device application (laparoscope). This submission included the cystourethroscope, cystoureteroscope, cystonephroscope for GU indications and the hysteroscope for OB/GYN indications. The revised indications for use are the following:

The Prosurg's NeoScope (Cystourethroscope /Cystoureteroscope /Cystonephroscope) Digital Video System (which includes the Digital video Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Urinary tract, and can be percutaneously to examine the interior of the kidney and using additional accessories can be used to perform various diagnostic and therapeutic procedures.

The Prosurg's Neoscope (Hysteroscope) Digital Video System (which includes the Digital Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Gynecological tract, and can be percutaneously to examine the interior of the uterus and using additional accessories can be used to perform various diagnostic and therapeutic procedures.

*FDA Response:*

*The sponsor has change tine indications for use to include only GU and OB/GYN indications. This can be found in K120766/ S1 on the Indications for Use page and in the labeling. This response is adequate.*

**V. Predicate Device Comparison**

The sponsor has provided minimal predicate comparison to the subject device.

**FDA Concern:**

**You have provided a limited comparison between your devices and the predicate device to determine substantial equivalence. In order to support the substantial equivalence of your proposed devices and the predicate devices you identify in your 510(k), please provide a detailed tabular comparison of the specifications of your devices and the predicates. For devices with the same intended use as the predicate devices, we would expect to see the comparisons in terms of indications for use, technology, physical dimensions, materials, design and performance specifications including any testing. And, a discussion as to whether those characteristics are the same as the predicates or if they are different, why those differences do not raise new questions of safety and effectiveness and demonstrates that the proposed devices are at least as safe and effective as the legally marketed devices.**

Specifications	Prosurg, Inc. NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) K120766 (subject device)	Prosurg, Inc. NeoScope™ Endoscopic Diagnostic & Treatment System K042780
<b>Indications for Use</b>	<p>(Cystourethroscope /Cystoureteroscope /Cystonephroscope) Digital Video System (which includes the Digital video Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Urinary tract, and can be percutaneously to examine the interior of the kidney and using additional accessories can be used to perform various diagnostic and therapeutic procedures.</p> <p>(Hysteroscope) Digital Video System (which includes the Digital Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Gynecological tract, and can be percutaneously to examine the interior of the uterus and using additional accessories can be used to perform various diagnostic and therapeutic procedures.</p>	Is intended for Cystoscopic, Hysteroscopic, Laparoscopic , Resectoscopic and Endoscopic treatment of Urological, Gynecological, Gastroenterological disorders and diseases of Prostate, Bladder, Urethra, Uterine cavity, Stomach, GI, Urinary tract and Reproductive organs using Biomaterials, Laser & RF devices, Tissue ablative and Augmenting agents, Microsurgical instruments and Endoscopic accessories.
<b>Materials:</b>		
<b>Sheath</b>	Stainless steel / TFE	Stainless steel / TFE
<b>Distal end</b>	Quartz Glass	Quartz Glass
<b>Dimensions:</b>		
<b>Diameter (mm)</b>	5.0 mm, 7.5 mm,	1.0 mm – 12.0 mm
<b>Length (cm)</b>	28 cm – 36 cm	10 cm – 45 cm
<b>Viewing Angle</b>	0 & 30°	0, 12, & 30°
<b>Use</b>	Single use	Reusable
<b>Sterility</b>	Supplied sterile	Supplied sterile

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

*FDA Response:*

*This response is adequate.*

## **VI. Labeling**

The sponsor has provided minimal labeling for the subject device.

### **FDA Concern:**

**You should include instructions for use in addition to the labeling provided which addresses:**

- a. The intended use statement should include specific indications for use, clinical setting, a defined target population, etc. In your case you would have to provide separate labeling for each type of endoscope including the accessories you plan to provide.**
- b. Directions for use should include:**
  - i) instructions on how to prepare each type of endoscope for patient use;**
  - ii) how to insert and remove each type of endoscope;**
  - iii) other specific physician labeling as to the principles of operation for each type of endoscope and accessories for each type of endoscope you plan to provide;**
  - iv) a statement of whether each type of endoscope is intended as single use/disposable or reusable. If endoscope is to be labeled as reusable for the same patient, provide adequate instructions about how to clean and sterilize the endoscope, as well as validation as to anticipated changes in device function secondary to reprocessing (e.g., change in antimicrobial status). Functional test procedures for the endoscope prior to use should also be provided, e.g., optical functioning. A separate reprocessing manual may be required**
  - v) A separate user's manual may be required for the principles of operation of each type of endoscope including the accessories.**
- c. Contraindications, precautions, warnings, and adverse effects should be included within the labeling for each type of endoscope including the accessories you plan to provide.**

See also Labeling Requirements, at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm>

Sponsor Response:

The Product labeling along with Instructions for Use has been revised for the proposed, single use, NeoScope Cystoscopes /Hysteroscope for Diagnosis and treatment of Urological disorders and Gynecological disorders. The Instructions for Use also includes revised Indications for use, Contraindications, Precautions, Warnings and potential adverse effects associated with the use of the device.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

*FDA Response:*

*The sponsor has changed the indications for use for the cystoscope and the hysteroscope. The Instructions for Use also includes revised Indications for use, Contraindications, Precautions, Warnings and potential adverse effects associated with the use of the device.*

*This can be found in K120766/S1 on pages 13 to 28. This response is adequate.*

**VII. Sterilization/Shelf Life/Reuse**

1. Sterilant:	YES	NO
<p>a. <b>Sterilization method</b> description (e.g., Steam (moist heat), EO, Radiation):</p> <p>b. <b>Dose</b>, for radiation (e.g., 25 – 50 kGy):</p> <p>c. <b>Sterilant residuals</b> remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the standards that have been, or currently are recognized, "ANSI/AAMI/ISO 10993-7:1995 and 2008 <i>Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals</i>," do not include measurement of ethylene glycol residuals);</p>	Ethylene oxide	
	N/A	
	EO – not > 20 mg per day ECH - not > 12 mg per day ETO gas levels were ≤ 0.3 mg / sample and ≤ 1 mg / sample respectively (5 days post sterilization)	
<p><b>2. A description of the Validation Method for the sterilization cycle (not data):</b> (Full citation of an FDA recognized standard is recommended including date (e.g., ANSI/AAMI/ISO 11135:2007)),</p>	ANSI/AAMI/ISO 11135:2007 and EN 550	
<p><b>3. Sterility assurance level (SAL):</b> (e.g., 10<sup>-6</sup> for all devices (except 10<sup>-3</sup> for devices that contact intact skin))</p>	10 <sup>-6</sup>	
<p><b>4. Is it labeled "Pyrogen Free"?</b></p> <p>If so, a description of the method: (e.g., LAL (<i>Limulus</i> Amebocyte Lysate test))</p>	Not stated	✓
	Limulus amebocyte lysate test	
<p><b>5. A description of the packaging</b> (not including package integrity test data):</p>	Blister Tray & Tyvek Lid Package	

**SHELF LIFE**

The sponsor reports that the shelf life for the device is one year, however, have not provided the reports to support a one year shelf life.

**FDA Concern:**

**You have stated that your shelf life determination is for 1 year for your device however, you have not included the reports to support your 1 year shelf life. Your shelf life should be supported by appropriate bench tests and/or sterilization and packaging validation. Please refer to the "Updated 501(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA available at the following web site:**

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<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm>

Sponsor Response:

The recommended Shelf life of the NeoScope™- Digital Video Endoscope System is one year. The product shelf life was determined as per Accelerated aging techniques, based on the assumptions that the chemical reactions involved in the deterioration of materials follow the Arrhenius reaction rate function. The sterilized products were subjected to environmental conditions & were tested to confirm product performance and packaging integrity specifications. The Shelf life Test Report is attached herewith for your review and approval. Time aging test for 12 month will be initiated out upon completion of first manufacturing production lot.

*FDA Response:*

*The sponsor has provided the following test results in the Shelf Life Report found in K120766/S1:*

**10. Test Results:**

*10.1 Product Visual & Functional Tests:*

*10.1.1 Visual Inspection of Neoscope™- Video Endoscope Products & Pkg*

*Visual Inspection Verified that the Neoscope™- Video Endoscopic System product, components, labels and packages were not damaged.*

*10.1.2 Functional Testing of Neoscope™- Video Endoscope Products & Pkg*

*(a) The functional testing of Neoscope™- Video endoscope products was carried out to confirm that they meet product specifications, including video imaging with connection to Video module & Laptop computer.*

*(b) Neoscope™-Video Endoscopic System passed all of the final product Dimensional and functional testing per QP 1130 & QP .1200.*

*10.1.3 Functional Testing of Neoscope™- Video Endoscope Packaging:*

*(a) Neoscope™- Video Endoscope Tyvek I Mylar pouch packages did not get damaged, melted, deformed, torn or broken during shelf life testing.*

*(b) Tyvek I Mylar pouch Packaging Seal integrity did not get damaged, torn or compromised ( peel strength) during shelf life testing.*

*(c) There were no holes, puncture or damage to Tyvek I Mylar pouch package ( dye check ) during shelf life testing .*

**11.0 RECOMMENDED SHELF LIFE:**

*Based on the result of Accelerated Ageing Test Method (ASTM F 1980: 2002) result, we have determined that Neoscope™-Video Endoscope products have a minimum one (1) year shelf life from*

*date of manufacturing. Please note that Product Sterility and Shelf life are in effect as long as the package is not opened or damaged.*

*This response is adequate.*

#### **VIII. Biocompatibility**

➤ **Comment:**

The sponsor reports that materials used to manufacture the subject device are identical to the predicate device and are safe and biocompatible materials that are widely used in the medical industry.

#### **FDA Concern:**

**You have stated that materials used to manufacture the subject device are identical to the predicate device and are safe and biocompatible materials that are widely used in the medical industry. Based on your statement, we cannot determine whether you have conducted biocompatibility testing of your final devices according to ISO 10993 standards. We would expect to see biocompatibility testing for limited contact of less than 24 hours to include but not limited to mucosal irritation or intracutaneous reactivity, cytotoxicity, and sensitization on your final sterilized devices Please note that the manufacturing process, including the sterilization process, can significantly affect the biocompatibility of the final device due to the use of different additives and the formation of various byproducts in manufacturing process.. Please clarify whether you have conducted biocompatibility testing of your final, finished, sterilized device as recommended by FDA blue book memo G95-1 and the ISO 10993-1:2009 standard. Please provide testing reports and standards forms for each testing if the test was conducted according to FDA recognized standards. Alternatively, please provide appropriate justification that your device is comprised of the exact same materials and exposed to the same manufacturing processes as the predicate device. Please refer to the guidance documents titled *Blue Book Memo, G95-1, Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices* which can be found at the following web site <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm>**

#### **Sponsor Response:**

The Biocompatibility Report for the NeoScope Diagnostic and Therapeutic Endoscopic System, as per limited Contact device (less than 24 hours) according to ISO 10993 standards has been attached herewith for your review. Please note that the Biocompatibility report includes Cytotoxicity, study ISO intracutaneous study and ISO maximization and Sensitization study for the Neoscope Diagnostic and Therapeutic Endoscopic System. Please note that the material, packaging manufacturing process, sterilization method & cycle are also identical. The Video module and laptop I Tablet computer being, not patient contact items are provided non sterile.

#### **FDA Response:**

*The sponsor has provided the biocompatibility testing of the Neoscope-Diagnostic & Therapeutic Endoscopic System. The results are summarized in following table, followed with in-depth review of each test. In depth review testing for Cytotoxicity, Irritation/Sensitization, and Maximization Sensitization Study was conducted and documented using the attached review templates that are provided by the Biocompatibility Quality Review program and upon review has met requirements for ISO 10993.*

<i>Test article</i>	<i>Test and method</i>	<i>Report # and page info</i>	<i>Review Summary</i>
<i>Neoscope-Diagnostic &amp; Therapeutic Endoscopic System from Prosurg., Inc.</i>	<i>Cytotoxicity – ISO Elution Method (1XMEM) Extract</i>  <i>Acceptable per checklist</i> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<i>NAMSA #C09877</i> <i>p. 6 of 8</i>	<i>Under the conditions of this study, the 1X MEM test extract showed no evidence of causing cell lysis or toxicity. The 1X MEM test extract met the requirements of the test since the grade was less than a grade2 (mild reactivity). The reagent control, negative control and positive control performed as anticipated.</i>
<i>Neoscope-Diagnostic &amp; Therapeutic Endoscopic System from Prosurg., Inc.</i>	<i>ISO Maximization Sensitization Study</i>  <i>Acceptable per checklist</i> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<i>NAMSA #C09877</i> <i>p. 8 of 13</i>	<i>Under the conditions of the study, The SC and SO test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.</i>
<i>Neoscope-Diagnostic &amp; Therapeutic Endoscopic System from Prosurg., Inc</i>	<i>ISO – Intracutaneous Study</i>  <i>Acceptable per checklist</i> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<i>NAMSA #C09877</i> <i>p. 7 of 9</i>	<i>Under the conditions of the study, There was no evidence of significant irritation from the extracts injected intracutaneously into rabbits. The Primary Irritation Index Characterization for the extracts was negligible.</i>

*This response is adequate.*

#### Standards

In K120766/S1 on page 33 it is reported that FDA Forms 3654 are submitted with this applications, however, these forms were not attached and need to be submitted.

#### *S1 Deficiency:*

*You have reported that your device is in compliance with several standards. The FDA-3654 Standards Data Report for 510(k)'s was recently made available on FDA's Internet website and should be provided in a 510(k) when a standard is referenced. This is required for all standards referenced in your submission. These forms are available to you in either portable document format (PDF) found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> Please complete this form for each standard cited in your 510(k) submission, for example, as found in Section 10 – Product Testing of your response to our June 25, 2012 additional information letter. This form is used to supply information suggested in the Recognition and Use of Consensus Standards; Final Guidance for Industry under the section entitled, Procedures for the Use of Consensus Standards, found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077274.htm>*

## **IX. Software**

### ➤ Comment:

Since the subject device incorporates a digital viewing endoscope with a LED light source and video module interface for display, operating software is needed. The sponsor needs to provide the software evaluation and performance validation according to the following software test requirements.

### **Software Test Requirements:**

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices includes the following:

- IEC 62304:2006 Medical Device Software - Software Life Cycle Processes
- <http://www.fda.gov/cdrh/ode/software.html>
- “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf>, 5/11/05
- “Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices”  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073779.pdf>, 9/9/1999
- “General Principles of Software Validation; Final Guidance for Industry and FDA Staff”  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085371.pdf>, 1/11/2002
- “Guidance for Industry. Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software”  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf>, 1/14/05

### **FDA Concern:**

**The sponsor needs to address the following software evaluation and performance requirements:**

### **Level of Concern**

**The firm should provide the level of concern, justification and supporting rationale.**

### **Software Description**

**Information should include a summary overview of the features and software operating environment including information on programming language, hardware platform, operating system and off-the-shell software.**

### **Software Hazard Analysis**

**Information should include a tabular description of identified hardware and software hazards,**

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including severity assessment and mitigation(s), clinical hazards, method of control of the hazards and results of evaluating the correct implementation.

**Software Requirements Specifications (SRS)**

Information should include a detailed listing of all of the specific requirements of the software including specifications of the functional requirements for the software in the digital video processor.

**Architecture Design Charts**

Information should include detailed depiction of functional units and software modules; it may also include state diagrams as well as flow charts.

**Software Design Specifications (SDS)**

This information should include a detailed SDS document, which describes how the SRS are implemented.

**Traceability Analysis**

This information should include traceability matrix among requirements, specifications, identified hazards and mitigation(s), including traceability information on risk mitigation measures and implementation of software design specifications, and verification and validation testing.

**Development Plan**

This information should include a summary of the software life cycle development plan, including the configuration management and maintenance plan documents. For a major level of concern, this documentation should also include an annotated list of control documents generated during the development process.

**Verification, Validation, and Testing**

For a minor level of concern, this documentation should include the software functional test plan, pass/fail criteria, and results. For a moderate level of concern, this documentation should include a description of verification and validation (V&V) activities at the unit, integration, and system level, as well as system level test protocol, including pass/fail criteria, and tests results. For a major level of concern, this information should include a description of V&V activities at the unit, integration, and system level as well as unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.

**Revision Level History**

Information should include a revision history log, including release version number and date to document the history of software revisions generated during the development of the software.

**Unresolved Anomalies (Bugs)**

For moderate and major, the documentation should include a list of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.

**Off-the-Shelf (OTS) Software**

The firm should provide information on any OTS software.

**Cyber and Information Security**

The firm should address security issues associated with network communications since the device may transmit endoscopic images to external servers (such as DICOM servers) via

network communications. The firm should also provide information, as appropriate, on the Cybersecurity aspects of their device, including but not limited to, the following facets of information security with respect to communications: confidentiality, integrity, availability and accountability.

Sponsor Response:

Prosurg states that the software for video processing is supplied by (b)(4) Company, and therefore, software evaluation and performance are not required. However, according to FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, the firm is still responsible for the continued safe and effective performance of their device using off-the-shelf (OTS) software.

FDA Response:

(b)(4)



**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

➤ Comment:

**Electromagnetic Compatibility**

The sponsor has not provided any information on the electromagnetic compatibility of their device to assess its safety and effectiveness.

**FDA Concern:**

**In order to evaluate the electromagnetic compatibility, safety, effectiveness, and reliability of your device according to EMC standard IEC 60601-1-2:2007–Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests – please provide the results of your testing and conclusions for those that are relevant to this standard. Additionally, please provide the following information in order to understand how the testing is performed:**

- a. A summary of the testing that was done;
- b. The requirements of the standard that were met (including immunity test levels);
- c. The pass/fail criteria used;

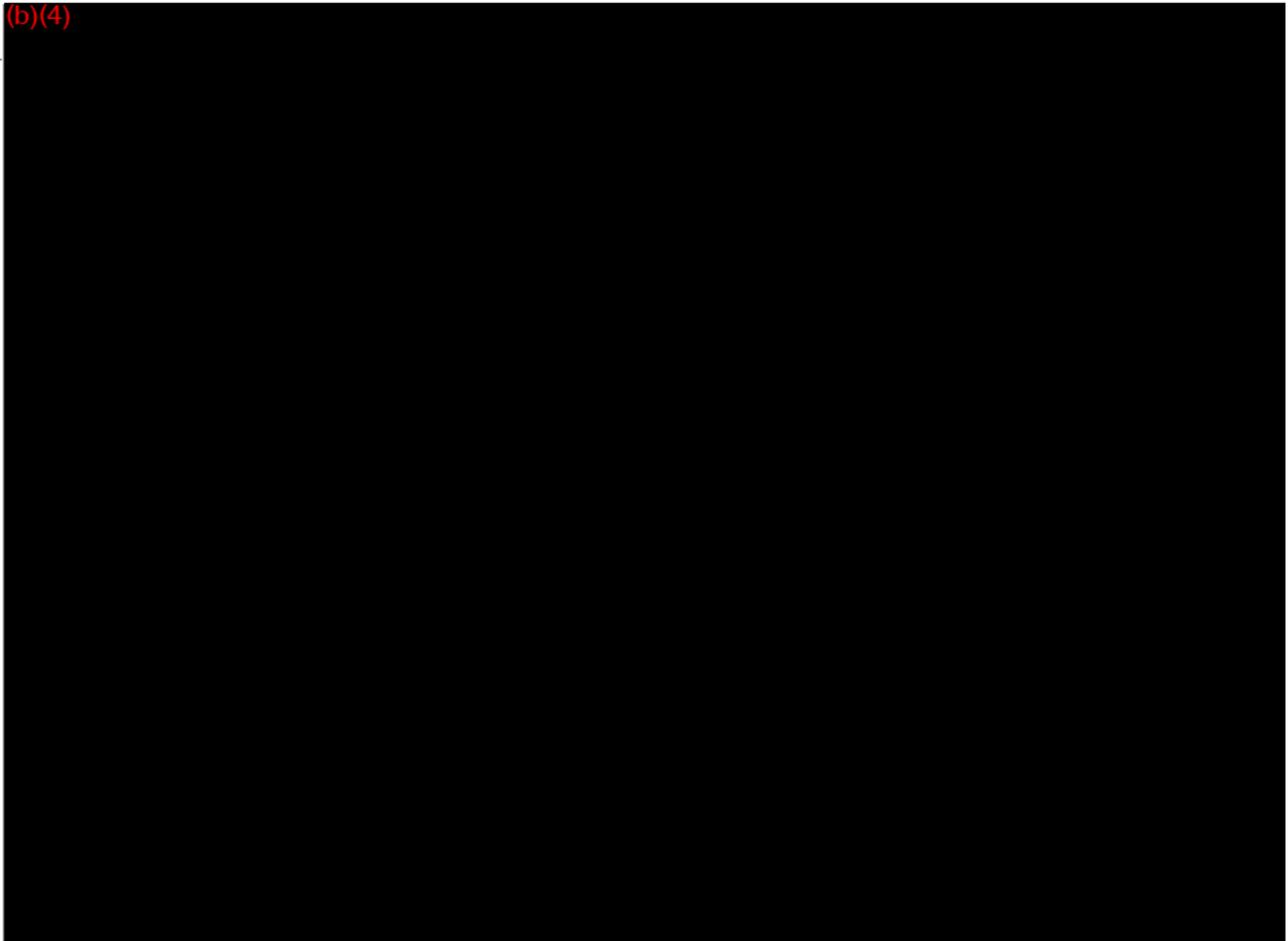
- d. **The functions of the device that were considered to be essential performance;**
- e. **The performance of the device during each immunity test (e.g., degradation observed);**
- f. **Identification and justification for any of the standard 's allowances that were used;**
- g. **A description of and justification for any deviations from the requirements of the standard;**
- h. **Evidence of compliance with the standard' s labeling (identification, marking and documents) requirements;**
- i. **If any device modifications were needed in order to pass any of the EMC testing, a description of these modifications and a statement that they will all be incorporated into the production units.**

Sponsor Response:

Prosurg states that their devices do not generate electromagnetic radiation and the imaging sensor is supplied by OmniVision. However, they indicate that their digital video endoscope design incorporates CMOS imaging sensor and LED at the distal end. According to EMC standard IEC 60601-1-2:2007-Part 1-2:2007, all electrical medical devices should conform to this consensus standard.

*FDA Response:*

(b)(4)



Sponsor Response:

Prosurg states that their device incorporates the imaging sensor supplied by OmniVision that meets IEC 60601-1-1:2000 and IEC 60601-2-18:1996&2000. As such they have adequately addressed this issue.

*FDA Response:*

*This response is adequate.*

**Mechanical Safety**

The sponsor did not provide any mechanical safety testing of their device to assess its safety and effectiveness.

**FDA Concern:**

**You did not provide a complete performance testing report summarizing the bench testing of your device and its outcomes, including the number of devices tested or if tests were performed on the final sterilized device. In order to determine the safety and effectiveness of your device please provide a complete report of your product performance testing, including but not limited to the following:**

- a. **Leak and pull testing;**
- b. **Handle strength testing.**

Sponsor Response:

Prosurg conducted the performance testing that includes pull force strength, leak, illumination, thermal and functional tests with the accompanying test report. As such they have adequately addressed this issue.

*FDA Response:*

*This can be found in the Test/Evaluation Report: Neoscope™ - Video Endoscope System in K120766/S1. This response is adequate.*

**Thermal Safety**

The sponsor did not provide any thermal safety testing to conform to the internationally recognized standards for thermal safety of medical electrical equipment.

**FDA Concern:**

**You did not provide the thermal safety testing of your device. In order to ensure that your device is thermally safe according to IEC 60601-2-18:1996 + A1:2000 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Endoscopic Equipment – please provide the results of your testing and conclusions for the device that applies to this performance standard.**

Sponsor Response:

Prosurg conducted the performance testing that includes pull force strength, leak, illumination, thermal and functional tests with the accompanying test report. As such they have adequately addressed this issue.

*FDA Response:*

*This can be found in the Test/Evaluation Report: Neoscope™ - Video Endoscope System in K120766/S1. This response is adequate.*

**XI. Performance Testing – Bench**

**FDA Concern:**

**You are modifying your device from a rod lens and fiber optic viewing endoscope with light source to a digital viewing endoscope which incorporates a miniature complementary medical oxide semiconductor (CMOS) imaging sensor and light emitting diodes (LEDs) located at the distal tip. Please provide data to demonstrate that the LEDs emit an amount of illumination that is either (i) equivalent to that emitted from the predicate endoscopes (using standard xenon light sources), or (ii) confirmed to be clinically acceptable for examination of the gastrointestinal tract. Currently, however, no comparison of illumination light intensity is provided.**

Sponsor Response:

Visualization / Imaging Test: (n=10)

Simulated visualization, LED lighting & Imaging Testing was carried out by connecting Neoscope, Video module and Laptop computer. The images and lighting were compared with conventional light source, Rod lens endoscope and TV monitor, and found to be of satisfactory quality for its intended use for endoscopic procedures. There was no heat build up due to LED lighting for period of 40 min exposure in fluid filled tissue cavity.

*FDA Response:*

*This can be found in the Test/Evaluation Report: Neoscope™ - Video Endoscope System in K120766/S1. This response is adequate.*

**XII. Performance Testing – Animal**

There are no animal testing requirements for this device.

**XIII. Performance Testing – Clinical**

There are no clinical testing requirements for this device.

**XIV. Substantial Equivalence Discussion**

	Yes	No	
1. Same Indication Statement?	✓		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	✓		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		✓	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?		✓	If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision: AI

Note: See

[http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0\\_4148/FLOWCHART%20DECISION%20TREE%20.DOC](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC) for Flowchart to assist in decision-making process.

Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

5. Explain how descriptive characteristics are not precise enough:

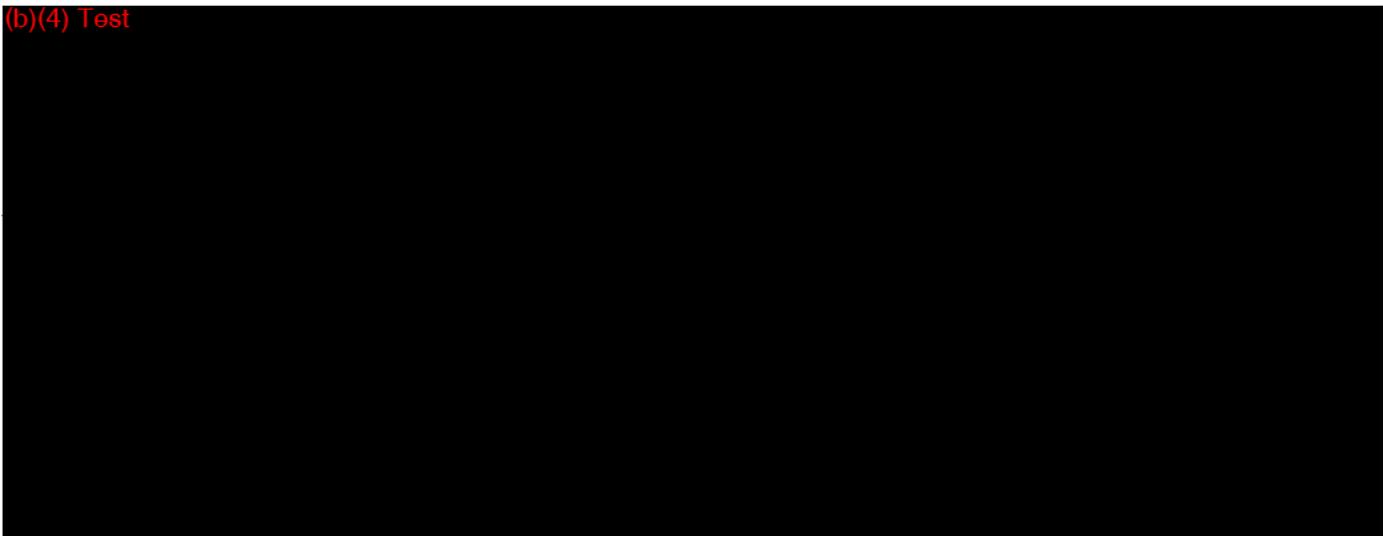
Standards forms, Software and EMC concerns remain.

8. Explain what performance data is needed:

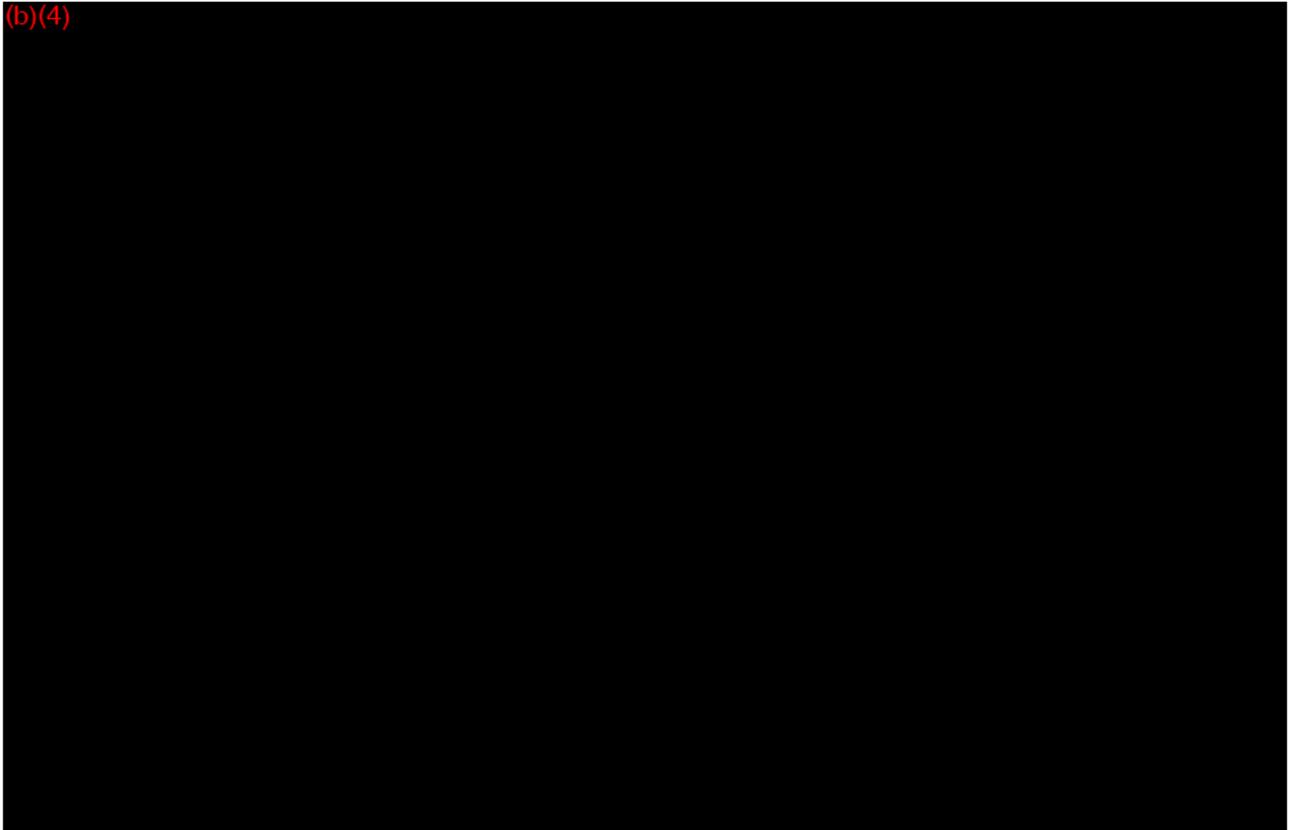
Standards forms, Software and EMC concerns remain.

**XV. Deficiencies**

(b)(4) Test



(b)(4)



**XVI. Contact History**

**K120766 dated 5 March 2012 received 8 May 2012**  
**K120766/S1 10 July 2012 received 18 July 2012**

**XVII. Recommendation: AI**

Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: Class II  
Product Code: FAJ

Mary E. Breen Anderson  
Reviewer  
James P. Seiler ACTING BC  
Branch Chief

14 August 2012  
Date  
8/15/2012  
Date



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**MEMORANDUM**

Food and Drug Administration  
Office of Device Evaluation  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

**Engineering Consult**

**K120766/S1**

Date: August 03, 2012  
To: Mary Beth O'Brien  
From: Tuan Nguyen *tn*  
CC: Glenn Bell  
510(k) Holder: ProSurg, Inc.  
Device Name: NeoScope™ Endoscopic Diagnostic & Treatment System (Modification)

**I. Purpose and Summary**

Per your request, I have reviewed the sponsor's responses to our AI request in this K120766/S001 submission that was received on July 18, 2012.

The major issues associated with the current K120766/S001 consist of the lack of safety and performance testing including electromagnetic compatibility and software testing. The current review of the current submission results in the request for additional information (AI) from ProSurg.

**II. Indications for Use**

The revised Indications-for-Use statements for both the subject device NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) and the predicate NeoScope™ Endoscopic Diagnostic & Treatment System are shown in the following table:

**TABLE 1 – INDICATIONS FOR USE**

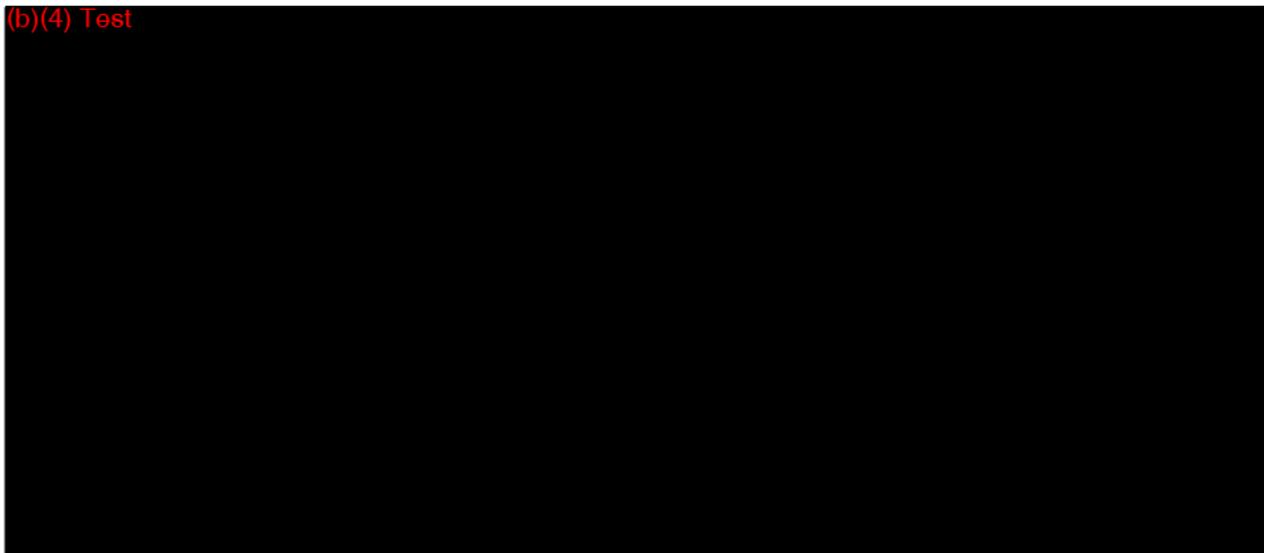
Subject Device	Predicate Device
NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) K120766	NeoScope™ Endoscopic Diagnostic & Treatment System K042780

<p><b>Original:</b>                  The NeoScope™ Endoscopic Diagnostic &amp; Treatment System (Modification) is intended for cystoscopic, hysteroscopic, laparoscopic, resectoscopic and endoscopic treatment of urological, gynecological, gastroenterological disorders and diseases of prostate, bladder, urethra, uterine cavity, stomach, GI, urinary tract and reproductive organs using biomaterials, laser and RF devices, tissue ablative and augmenting agents, microsurgical instruments and endoscopic accessories.</p>	<p><b>Revised:</b>                  The Prosurg's NeoScope (Cystourethroscope/ Cystonephroscope) Digital Video System (which includes the Digital video Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Urinary tract, and can be percutaneously to examine the interior of the kidney and using additional accessories can be used to perform various diagnostic and therapeutic procedures.                  The Prosurg's Neoscope (Hysteroscope) Digital Video System (which includes the Digital Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Gynecological tract, and can be percutaneously to examine the interior of the uterus and using additional accessories can be used to perform various diagnostic and therapeutic procedures.</p>	<p>The NeoScope™ Endoscopic Diagnostic &amp; Treatment System is intended for cystoscopic, hysteroscopic, laparoscopic, resectoscopic and endoscopic treatment of urological, gynecological, gastroenterological disorders and diseases of prostate, bladder, urethra, uterine cavity, stomach, GI, urinary tract and reproductive organs using biomaterials, laser and RF devices, tissue ablative and augmenting agents, microsurgical instruments and endoscopic accessories.</p>
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**Reviewer Comment:**

In the original submission, the sponsor provided an indications-for-use statement that did not incorporate all the functions or the indications of their device. They stated that their device could be used in a wide variety of procedures. For their urological and/or gastroenterological device application, a revision of the indications-for-use statement was needed to reflect the specific functions and indications for these uses.

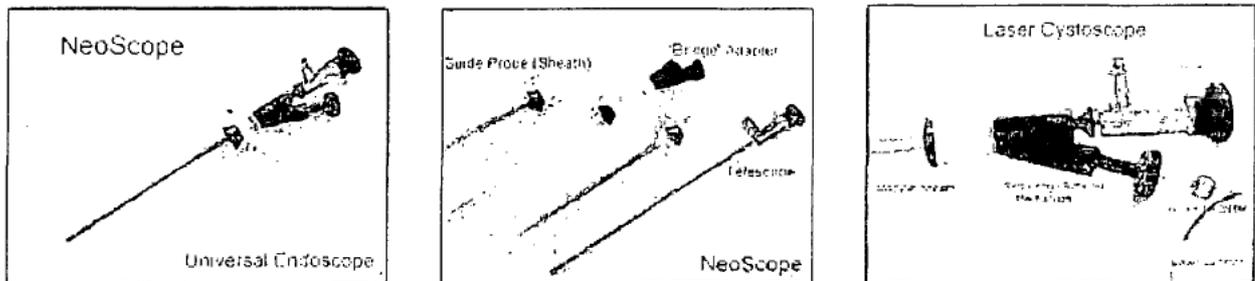
(b)(4) Test



(b)(4) Test

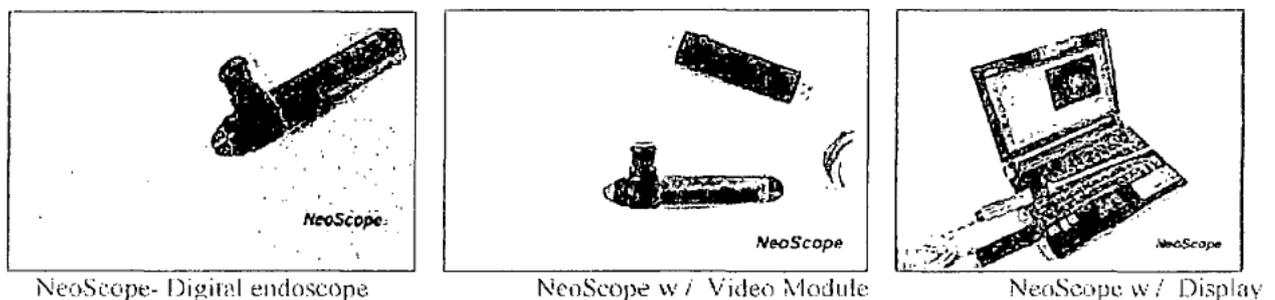
### III. Device Description

The NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) is a sterile, single-use modular device for endoscopic diagnostic and treatment. It is compatible with standard endoscopes and interchangeable accessories. The device consists of an outer guide probe, adapter, delivery system and a viewing scope. The outer guide probe is used for irrigation. The delivery system comprises the injection needle and probes for delivering treatment substance, tissue agents, imaging dyes and contrast agents, drugs, sclerosing agents and bio-toxins. It can also be used for delivering thermal energy for tissue ablation and removal using radio frequency (RF), laser, microwave energy, cryo energy. The device can be used in a variety of endoscopic functions such as cystoscope, resectoscope, nephroscope, hysteroscope, and laparoscope. The original NeoScope™ Endoscopic Diagnostic & Treatment System is shown in the following figure.



**Figure 1: The NeoScope™ Endoscopic Diagnostic & Treatment System**

The new NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) consists of a digital viewing endoscope with a LED light source and video module interface for display using commercially available monitoring devices. The new NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) with the proposed modification system is illustrated in the following figure.



**Figure 1: The NeoScope™ Endoscopic Diagnostic & Treatment System (Modification)**

The subject device is designed for optimal visualization via digital imaging technology and to allow fluid irrigation and microsurgical instrument access. It can be introduced through various body cavities and opening.

The following table summarizes the product specifications of the NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) along with their functions and descriptions.

**TABLE 2 – REVISED PRODUCT SPECIFICATIONS**

<b>Component/ Function</b>	<b>Description/Model</b>	<b>Material</b>
<b>Camera Sensor</b>	CMOS	Commercially Available
<b>Light Source</b>	LED	Commercially Available
<b>Conventional Viewing Endoscope</b>	Diameter: 1.0 mm Viewing Angle: 0°	Outer Tubing: Stainless Steel 304/306 Rod Lens Optics: Quartz
<b>Digital Endoscope (Rigid)</b>	Diameter: 5.0 mm Working Length: 28 cm Working Channel: 1.5 mm	Rigid Outer Sheath: Stainless Steel 316 Optical Window: Quartz Handle: ABS
<b>Digital Endoscope (Flexible)</b>	Diameter: 7.5 mm Working Length: 36 cm Working Channel: 1.5 mm	Flexible Outer Sheath: TFE Optical Window: Quartz Handle: ABS
<b>Accessories</b>	Video Interface Module Connecting Cable Video Display Monitor	Commercially Available
<b>Packaging</b>	Blister Tray Tyvek Lid Package	Commercially Available
<b>Usage</b>	Single Use Only	Supplied Sterile

**Reviewer Comment:**

The sponsor did not provide the detailed description of their device.

**Response to Original Deficiency**

Please provide a more detailed description of the device and its various configurations, including: (i) Identification and description of each component/accessory, including complete details regarding the thermal energy for tissue ablation and removal using RF (Monopolar / Bipolar), Laser, Microwave energy, Cryo energy and Microsurgical instrumentation), and (ii) A complete list of all compatible endoscope designs (currently listed as “Storz, Wolf, Circon/Gyrus/ACMI, Olympus & others,” which is open-ended).

*Prosurg provides a detailed device description of their devices that include digital video endoscope, video module and software, laptop/tablet computer, and as such they have adequately addressed this issue.*

**IV. Device Comparison**

**Reviewer Comment:**

The sponsor did not provide the device comparison between the subject and predicate devices.

**Response to Original Deficiency**

(b)(4) Test



## V. Software

### **Reviewer Comment:**

Since the subject device incorporates a digital viewing endoscope with a LED light source and video module interface for display, operating software is needed. The sponsor needs to provide the software evaluation and performance validation according to the following software test requirements.

### **Software Test Requirements:**

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices includes the following:

- IEC 62304:2006 Medical Device Software - Software Life Cycle Processes
- <http://www.fda.gov/cdrh/ode/software.html>
- "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf>, 5/11/05
- "Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices" <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073779.pdf>, 9/9/1999
- "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085371.pdf>, 1/11/2002
- "Guidance for Industry. Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software" <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf>, 1/14/05

### **Response to Original Deficiency**

The sponsor needs to address the following software evaluation and performance requirements:

#### **Level of Concern**

The firm should provide the level of concern, justification and supporting rationale.

#### **Software Description**

Information should include a summary overview of the features and software operating environment including information on programming language, hardware platform, operating system and off-the-shell software.

#### **Software Hazard Analysis**

Information should include a tabular description of identified hardware and software

hazards, including severity assessment and mitigation(s), clinical hazards, method of control of the hazards and results of evaluating the correct implementation.

**Software Requirements Specifications (SRS)**

Information should include a detailed listing of all of the specific requirements of the software including specifications of the functional requirements for the software in the digital video processor.

**Architecture Design Charts**

Information should include detailed depiction of functional units and software modules; it may also include state diagrams as well as flow charts.

**Software Design Specifications (SDS)**

This information should include a detailed SDS document, which describes how the SRS are implemented.

**Traceability Analysis**

This information should include traceability matrix among requirements, specifications, identified hazards and mitigation(s), including traceability information on risk mitigation measures and implementation of software design specifications, and verification and validation testing.

**Development Plan**

This information should include a summary of the software life cycle development plan, including the configuration management and maintenance plan documents. For a major level of concern, this documentation should also include an annotated list of control documents generated during the development process.

**Verification, Validation, and Testing**

For a minor level of concern, this documentation should include the software functional test plan, pass/fail criteria, and results. For a moderate level of concern, this documentation should include a description of verification and validation (V&V) activities at the unit, integration, and system level, as well as system level test protocol, including pass/fail criteria, and tests results. For a major level of concern, this information should include a description of V&V activities at the unit, integration, and system level as well as unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.

**Revision Level History**

Information should include a revision history log, including release version number and date to document the history of software revisions generated during the development of the software.

**Unresolved Anomalies (Bugs)**

For moderate and major, the documentation should include a list of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.

**Off-the-Shelf (OTS) Software**

The firm should provide information on any OTS software.

**Cyber and Information Security**

The firm should address security issues associated with network communications since the device may transmit endoscopic images to external servers (such as DICOM servers) via network communications. The firm should also provide information, as appropriate, on the Cybersecurity aspects of their device, including but not limited to, the following facets of information security with respect to communications: confidentiality, integrity, availability and accountability.

*Prosurg states that the software for video processing is supplied by El Gato Company, and therefore, software evaluation and performance are not required. However, according to FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, the firm is still responsible for the continued safe and effective performance of their device using off-the-shelf (OTS) software.*

***S1 Deficiency:***

You state that the software for video processing is supplied by El Gato Company, and therefore, software evaluation and performance are not required. We respectfully disagree with your statement. According to FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, you are still responsible for the continued safe and effective performance of their device using off-the-shelf (OTS) software. Please provide information of any OTS software used in your devices following the "Guidance for Industry. Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software" <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf>, 1/14/05

**VI. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

**Electromagnetic Compatibility**

The sponsor did not provide the electromagnetic compatibility evaluation of their device to assess its safety and effectiveness.

**Response to Original Deficiency**

**In order to evaluate the electromagnetic compatibility, safety, effectiveness, and reliability of your device according to EMC standard IEC 60601-1-2:2007–Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests – please provide the results of your testing and conclusions for those that are relevant to this standard. Additionally, please provide the following information in order to understand how the testing is performed:**

- a. **A summary of the testing that was done;**
- b. **The requirements of the standard that were met (including immunity test levels);**
- c. **The pass/fail criteria used;**
- d. **The functions of the device that were considered to be essential performance;**
- e. **The performance of the device during each immunity test (e.g., degradation observed);**
- f. **Identification and justification for any of the standard 's allowances that were used;**
- g. **A description of and justification for any deviations from the requirements of the standard;**
- h. **Evidence of compliance with the standard' s labeling (identification, marking and documents) requirements;**
- i. **If any device modifications were needed in order to pass any of the EMC testing, a description of these modifications and a statement that they will all be incorporated into the production units.**

*Prosurg states that their devices do not generate electromagnetic radiation and the imaging sensor is supplied by OmniVision. However, they indicate that their digital video endoscope design incorporates CMOS imaging sensor and LED at the distal end. According to EMC standard IEC 60601-1-2:2007–Part 1-2:2007, all electrical medical devices should conform to this consensus*

standard.

**S1 Deficiency:**

You state that your devices do not generate electromagnetic radiation and the imaging sensor is supplied by OmniVision. However, you indicate that your digital video endoscope design incorporates CMOS imaging sensor and LED at the distal end. According to EMC standard IEC 60601-1-2:2007–Part 1-2:2007, all electrical medical devices should conform to this consensus standard. Please provide the electromagnetic compatibility evaluation of your devices to assess their safety and effectiveness in the proximity of other electrical medical devices. Please also provide the results of your testing and conclusions for those that are relevant to this standard.

**Electrical Safety**

The sponsor did not provide any electrical safety testing to conform to the internationally recognized standards for electrical safety of medical electrical equipment.

**Response to Original Deficiency**

**You did not provide the electrical safety testing of your device under normal conditions and under the operating conditions which include the use of specified electrical surgical units. In order to ensure that your device is electrically safe according to IEC 60601-1-1:2000 Medical Electrical Equipment – Part 1-1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems and IEC 60601-2-18:1996 + A1:2000 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Endoscopic Equipment – please perform the electrical safety testing of your active device with compatible electrosurgical units and connectors and revise your instructions for use to include compatible electrosurgical units. Please also provide the input parameters of your device that is required to achieve your specified output parameters.**

*Prosurg states that their device incorporates the imaging sensor supplied by OmniVision that meets IEC 60601-1-1:2000 and IEC 60601-2-18:1996&2000. As such they have adequately addressed this issue.*

**Mechanical Safety**

The sponsor did not provide any mechanical safety testing of their device to assess its safety and effectiveness.

**Response to Original Deficiency**

**You did not provide a complete performance testing report summarizing the bench testing of your device and its outcomes, including the number of devices tested or if tests were performed on the final sterilized device. In order to determine the safety and effectiveness of your device please provide a complete report of your product performance testing, including but not limited to the following:**

- a. Leak and pull testing;
- b. Handle strength testing.

*Prosurg conducted the performance testing that includes pull force strength, leak, illumination, thermal and functional tests with the accompanying test report. As such they have adequately addressed this issue.*

**Thermal Safety**

The sponsor did not provide any thermal safety testing to conform to the internationally recognized standards for thermal safety of medical electrical equipment.

**Response to Original Deficiency**

**You did not provide the thermal safety testing of your device. In order to ensure that your device is thermally safe according to IEC 60601-2-18:1996 + A1:2000 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Endoscopic Equipment –**

**please provide the results of your testing and conclusions for the device that applies to this performance standard.**

*Prosurg conducted the performance testing that includes pull force strength, leak, illumination, thermal and functional tests with the accompanying test report. As such they have adequately addressed this issue.*

## **VII. Performance Testing – Bench**

### **Optical Performance**

The sponsor did not provide the optical performance of their device to conform to the internationally recognized standards for optics and optical performance of medical electrical equipment.

### **Response to Original Deficiency**

**You did not provide the optical performance evaluation of your device. In order to evaluate the optical performance, safety, effectiveness, and reliability of your devices according to ISO 8600-1-5 – Optics and Photonics – please provide the results of your testing and conclusions for those devices that are relevant to this performance standard.**

*Prosurg conducted the performance testing that includes pull force strength, leak, illumination, thermal and functional tests with the accompanying test report. As such they have adequately addressed this issue.*

### **Risk Analysis**

The sponsor did not provide the risk management to conform to the internationally recognized standards for risk management of medical electrical equipment.

### **Response to Original Deficiency**

**You did not provide the risk analysis of your device. In order to identify the hazards associated with your device, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls according to ISO 14971:2007 – Risk Analysis, please provide the results of your risk analysis and conclusions that your device is safe.**

*The sponsor did not address this deficiency and it still remains an issue.*

### **S1 Deficiency:**

You did not provide the risk analysis of your devices. In order to identify the hazards associated with your devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls according to ISO 14971:2007 – Risk Analysis, please provide the results of your risk analysis and conclusions that your devices are safe.

### **Recommended S1 Deficiencies:**

The following deficiencies are identified with the information submitted by the sponsor:

1. You state that the software for video processing is supplied by El Gato Company, and therefore, software evaluation and performance are not required. We respectfully disagree with your statement. According to FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, you are still responsible for the continued safe and effective performance of their device using off-the-shelf (OTS) software. Please provide information of any OTS software used in your devices following the "Guidance for Industry. Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software."  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf>, 1/14/05

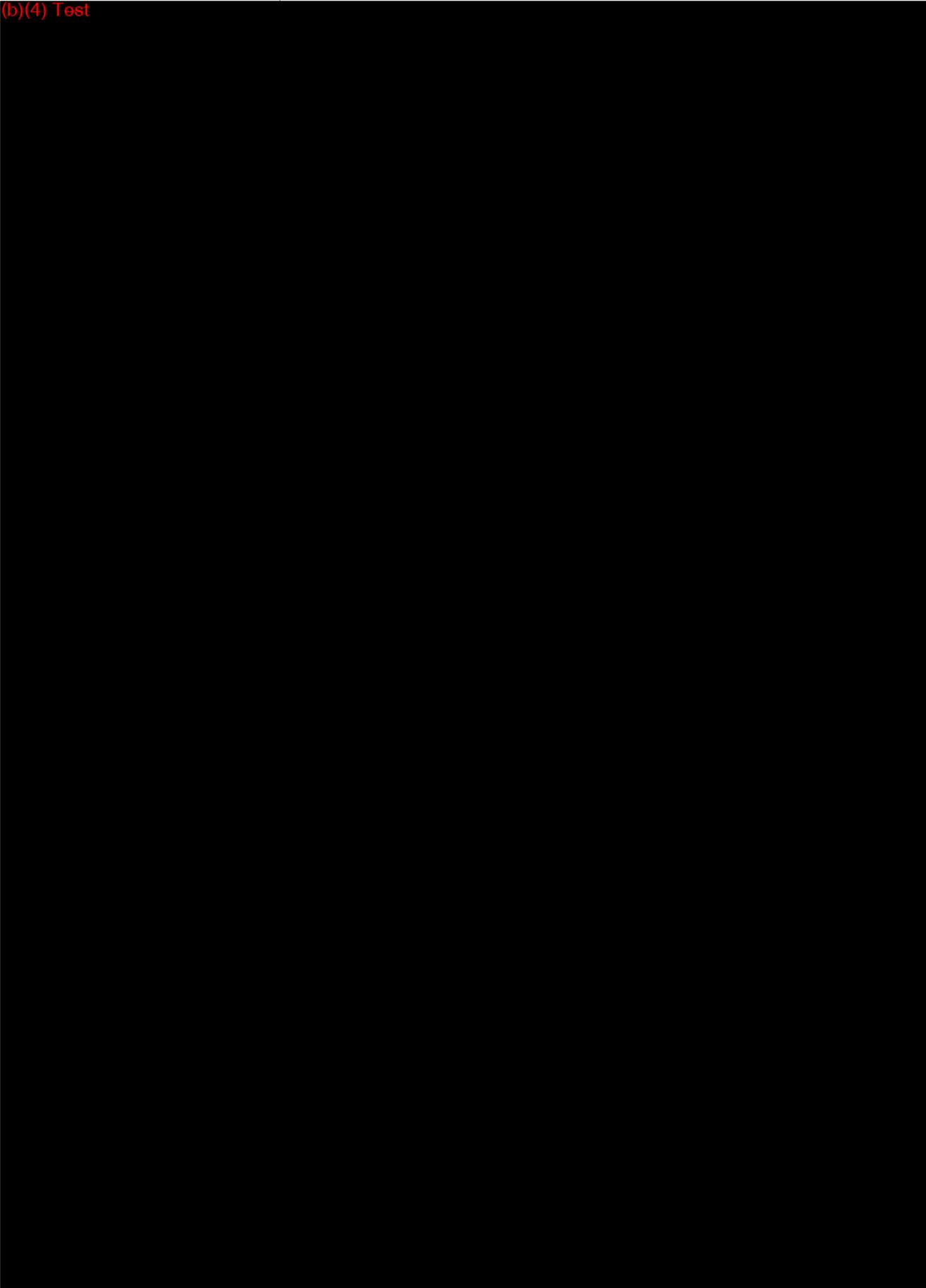
2. You state that your devices do not generate electromagnetic radiation and the imaging sensor is supplied by OmniVision. However, you indicate that your digital video endoscope design incorporates CMOS imaging sensor and LED at the distal end. According to EMC standard IEC 60601-1-2:2007–Part 1-2:2007, all electrical medical devices should conform to this consensus standard. Please provide the electromagnetic compatibility evaluation of your devices to assess their safety and effectiveness in the proximity of other electrical medical devices. Please also provide the results of your testing and conclusions for those that are relevant to this standard.
3. You did not provide the risk analysis of your devices. In order to identify the hazards associated with your devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls according to ISO 14971:2007 – Risk Analysis, please provide the results of your risk analysis and conclusions that your devices are safe.

#### **VIII. Recommendation**

Additional information is needed to determine if the subject device NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) is substantially equivalent to the predicate NeoScope™ Endoscopic Diagnostic & Treatment System. A letter with the list of deficiencies should be sent to the sponsor.

Tuan Nguyen, Ph.D.

(b)(4) Test





















U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

July 18, 2012

PROSURG, INC.  
2195 TRADE ZONE BLVD.  
SAN JOSE, CALIFORNIA 95131  
ATTN: A. DESAI

510k Number: K120766

Product: ENDOSCOPIC DIAGNOSTIC &

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

**Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.**

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

FAX HEADER 1:  
FAX HEADER 2:

TRANSMITTED/STORED : JUL. 18. 2012 12:25PM  
FILE MODE OPTION

ADDRESS

RESULT

PAGE

7 MEMORY TX 4089451390 OK 1/1

REASON FOR ERROR  
E-1) HANG UP OR LINE FAIL  
E-3) NO ANSWER

E-2) BUSY  
E-4) NO FACSIMILE CONNECTION



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center W066-0609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

July 18, 2012

PROSURG, INC.  
2195 TRADE ZONE BLVD.  
SAN JOSE, CALIFORNIA 95131  
ATTN: A. DESAI

510k Number: K120766

Product: ENDOSCOPIC DIAGNOSTIC &

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

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Sincerely,

510(k) Staff

K120766/S1

FDA CDRH DMC

JUL 18 2012

**ProSurg**

Received

Date : July 10, 2012

K12  
~~FDA CDRH DMC~~

~~JUL 17 2012~~

~~Received~~

Attn: Mary Beth O'Brien RN, MSN  
Food & Drug Administration  
Division of reproductive, Gastro -Renal & Urological Devices  
Office of Device Evaluation  
Center for Devices & Radiological Health  
10903 New Hampshire Avenue  
Document Control Room - W066-G0609  
Silver Spring MD 20993-002

Re : 510K - K120766 Application - NeoScope™  
Endoscopic Diagnostic & Treatment System ( Modification)

Dear Ms Mary Beth O'Brien,

Based On telephone conversation, I would like to submit additional information and explanation to clarify of some of the questions raised by you regarding above mentioned 510 K application.

**(1) Device Description: - NeoScope Cystoscope / Hysteroscope**

The NeoScope Video Endoscopic System consists of three main components:

- (a) Digital Video Endoscope ( ProSurg Inc )
- (b) Video Module & Software ( El Gato Company)
- (c) Laptop / Tablet Computer ( Mac , window Computer Companies)

**Digital Video Endoscope ( Rigid /Flexible)**

The Digital Video endoscope design incorporates a CMOS imaging sensor and 4 ea built-in LED ( Light Emitting Diodes) mounted at the distal end , connecting wires along the length of the hollow tubular structure and a USB 2.0 Connector at the proximal end. The distal end of

**PROSURG, INC.**

2193 Trade Zone Blvd. San Jose, CA 95131

Tel: (408) 945-4044, 1-800-200-SURG Fax: (408) 945-1390

Questions? Contact FDA/CDRH/OCE/DID at [CDRH@FDA.USDOH](mailto:CDRH@FDA.USDOH) or 301-796-8118

the endoscope containing CMOS sensor and LEDs, is protected by sealed optical glass window and the proximal end of the tubular structure is housed into a medical grade ABS molded handle. The Neoscope endoscope is provided sterile for Single use only and does not require cleaning , reprocessing or re-sterilization. The Neoscope Endoscope is available as a 5.0mm OD diagnostic device or 7.5mm OD as an operating device with 5 Fr working channel. The Neoscope can be utilized as a Cystoscope or Hysteroscope by a trained physican for diagnostic and operating procedures, using commercially available, video capture module and portable laptop / Tablet computer.

*( Please refer to attached drawings for additional details )*

### **Video Capture Module & Software \*:**

The Video Capture Module and Video Processing Software , commonly used to covert Analog video (VCR) tapes & other media into Digital files or DVD are supplied by (b)(4) company for use with majority of commercial computers. The Video Capture module with software are not patient contact items and can easily be connected / loaded to the Laptop/ Tablet computer. The Video Capture Module receives the analog signal from CMOS sensor of the endoscope and coverts it into digital video signal recordings. The El Gato software is used to format the digital video recordings into commonly used video format files, including Quick Time, iTune, i Movie, window Media & You Tube.

- Note: The Video module and Software are commercially available products ( (b)(4) Company) and are non patient contact items. (Supplied Non Sterile)

### **Portable Laptop / Tablet Computers:**

The Portable Laptop / Tablet Computer can be used as a video monitor and recording / storage device to view, record , edit, store and transfer /transmit the video files. The Digital Video Endoscope and Video Capture Module can be connected to majority of all commercially available Laptop /Tablet computer using standard USB 2.0 connecting cables. If necessary, additional USB connecting cable can also be used.

\* Note: The Laptop / Tablet Computer is commercially available product ( Mac or Window based Operating System) and is a non patient contact item. (Not supplied)

**NeoScope Product Configurations : ( Rigid / Flexible)**

In order to simplify the review of proposed 510 k Application, we would like to limit submission to only following product Configurations of NeoScope Digital Video Endoscope.

**Cystoscopes / Hysteroscope for Diagnosis and treatment of Urological disorders and Gynecological disorders.**

*Please note that the proposed Digital Video Endoscopes are supplied sterile, for single use only and does not require cleaning, reprocessing or re sterilization.*

**NeoScope Product Models :**

**NeoScope -Digital Video Cystoscopes & Hysteroscopes ( Rigid / Flexible)**

<b>Model #</b>	<b>Product Description</b>
NCR50S	Diagnostic Neo-Cystoscope (5.0mm Dia, 28 cm long)
NCR75S	Operating Neo-Cystoscope (7.5mm Dia, 28 cm long)
NHR50S	Diagnostic Neo-Hysteroscope (5.0mm Dia, 28 cm long)
NHR75S	Operating Neo-Hysteroscope (7.5mm Dia, 28 cm long)
NCF75 S	Operating NeoFlex-Cystoscope (7.5mm Dia, 28 cm long)
NHF75S	Operating NeoFlex-Hysteroscope (7.5mm Dia, 28 cm long)

*Note: The Cystoscope and Hysteroscope models are identical in design, dimensions and configurations.*

**(1a) Components & Accessories: ( Clarification )**

The proposed 510k application is only for NeoScope -Digital Video Endoscope System and does not include any micro instruments, RF probes, Laser Fiberoptics, Microwave or Cryo energy delivery devices or other accessories to be supplied by Prosurg, Inc.

The working channel provided in the video endoscope is for suction and irrigation of fluid, commonly used during endoscopic procedure. The working channel can also be used to insert commercially available (FDA approved) micro instruments and accessories ( max Size 5.0 Fr).

(1b) The NeoScope – Digital Video Endoscope device is compatible with commercially available Rigid /Flexible Cystoscopes, and Hysteroscope components, instrumentations/ Accessories marketed by Storz, Wolf, Olympus, Circon / ACMI / Gyrus. The Neoscope can also be used with commercially available Suction / Irrigation systems for endoscopic use.

**(2) Predicate Comparison :**

To establish substantial equivalency of proposed device with predicate devices , a revised comparison matrix outlining proposed Product Specifications, Technology, Dimensions and Indications for Use with the Predicate devices is attached for your review.

*( Please see attached Comparison matrix)*

**(3) Product Labeling :**

The Product labeling along with Instructions for Use has been revised for the proposed Single use, NeoScope Cystoscopes / Hysteroscope for Diagnosis and treatment of Urological disorders and Gynecological disorders. The Instructions for Use also includes revised Indications for use, Contraindications, Precautions, Warnings and potential adverse effects associated with the use of the device.

*( Please see attached Product Labeling and Instructions for Use)*

**(4) Product Shelf Life:**

The recommended Shelf life of the NeoScope™- Digital Video Endoscope System is one year. The product shelf life was determined as per Accelerated aging techniques, based on the assumptions that the chemical reactions involved in the deterioration of materials follow the Arrhenius reaction rate function. The sterilized products were subjected to environmental conditions & were tested to confirm product performance and packaging integrity specifications. The Shelf life Test Report is attached herewith for your review and approval. The Real –

Time aging test for 12 month will be initiated out upon completion of first manufacturing production lot.

**(5) Biocompatibility :**

The Biocompatibility Report for the NeoScope Diagnostic and Therapeutic Endoscopic System , as per limited Contact device ( less than 24 hours ) according to ISO 10993 standards has been attached herewith for your review. Please note that the Biocompatibility report includes Cytotoxicity, study ISO intracutaneous study and ISO maximization and Sensitization study for the Neoscope Diagnostic and Therapeutic Endoscopic System. Please note that the material, packaging manufacturing process, sterilization method & cycle are also identical. The Video module and laptop / Tablet computer being, not patient contact items are provided non sterile.

**(6) Software :**

The software for video processing and formatting is commercially available software, supplied by (b)(4) company. Prosurg does not supply the software for use with Neoscope - Video Endoscopy system.

**(7) Electromagnetic Compatibility:**

The Neoscope device does not generate any electromagnetic radiation. The specifications of Imaging sensor, supplied by (b)(4) (b)(4) is attached herewith for your review.

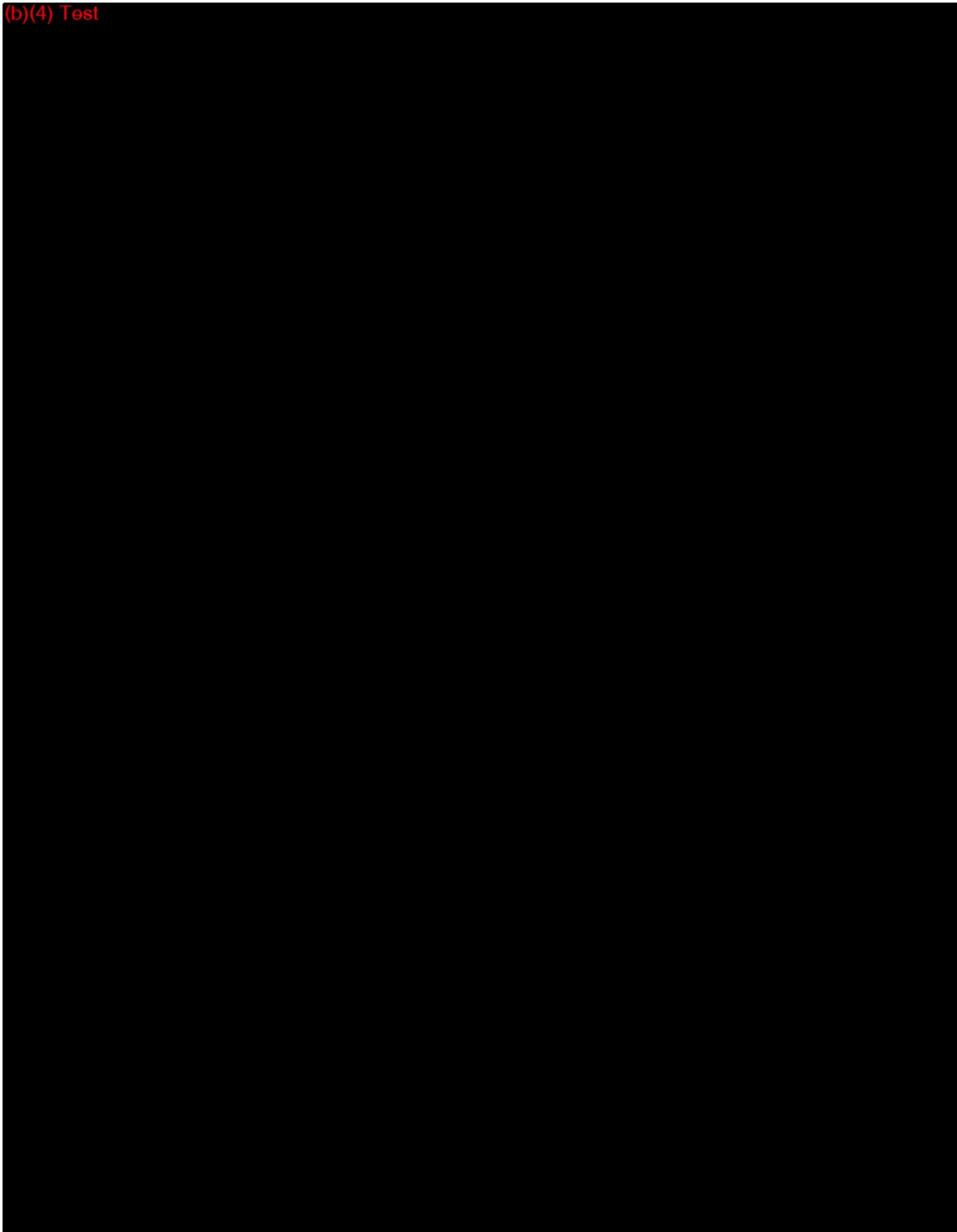
**(8) Electrical Safety:** The Imaging sensor from (b)(4) (b)(4) is powered by 3.3V DC power source of laptop / Tablet computer and meets IEC 60601-1 -1 : 2000 and IEC 60601-2-18:1996 & 2000. The Neoscope video Endoscope does not contain any battery or other Electrical power source. The Video Module also does not contain any power source. Please note that commercially available Laptop / Tablet computers meets all of the Electrical safety standards.

**(9) Mechanical / Performance Safety Testing :**

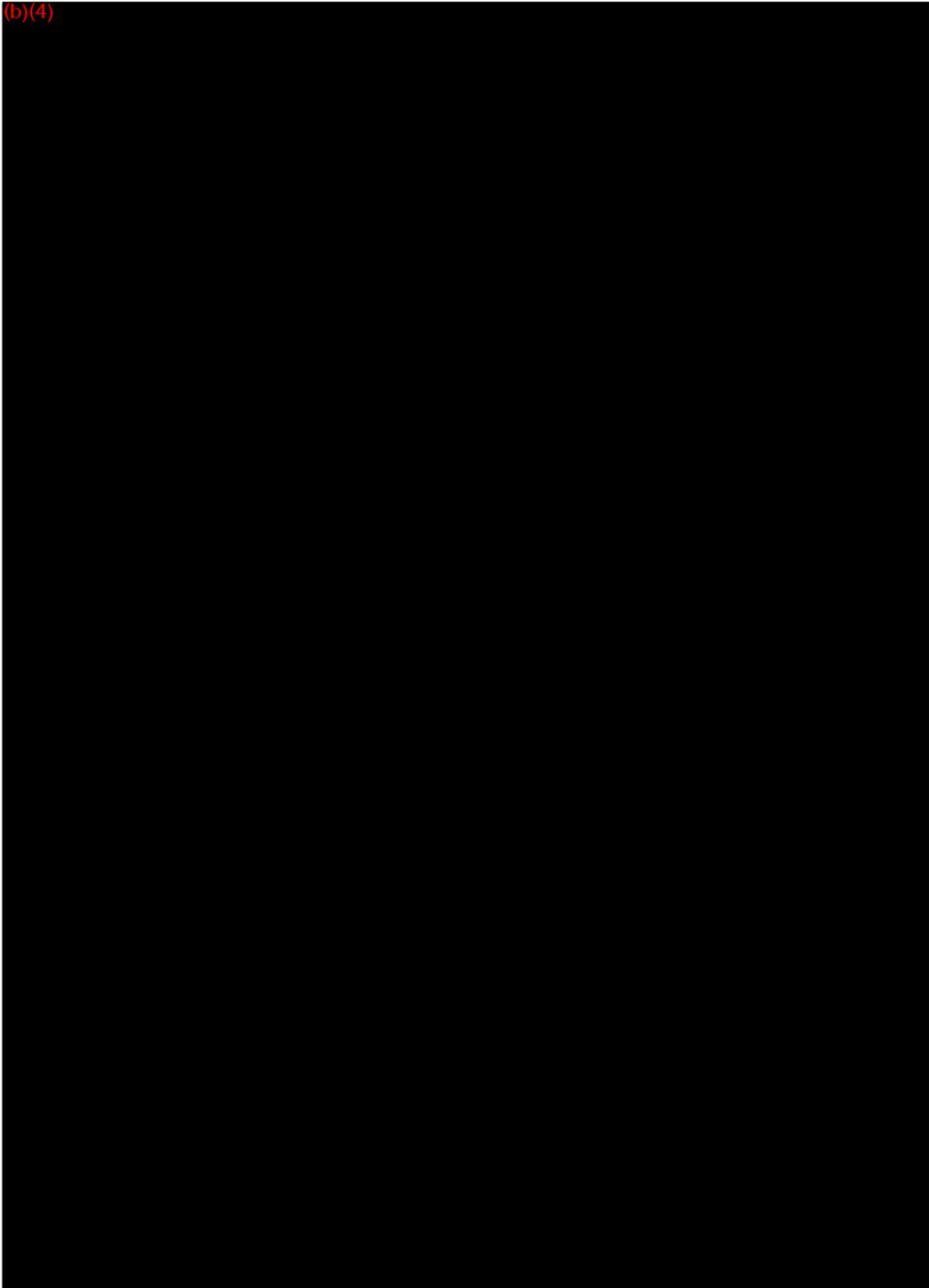
The performance testing , including pull force strength , leak test, Illumination testing and functional testing was carried out for Neoscope video endoscopic system. The test result report is attached herewith for your review.

**Prosurg, Inc.**

(b)(4) Test

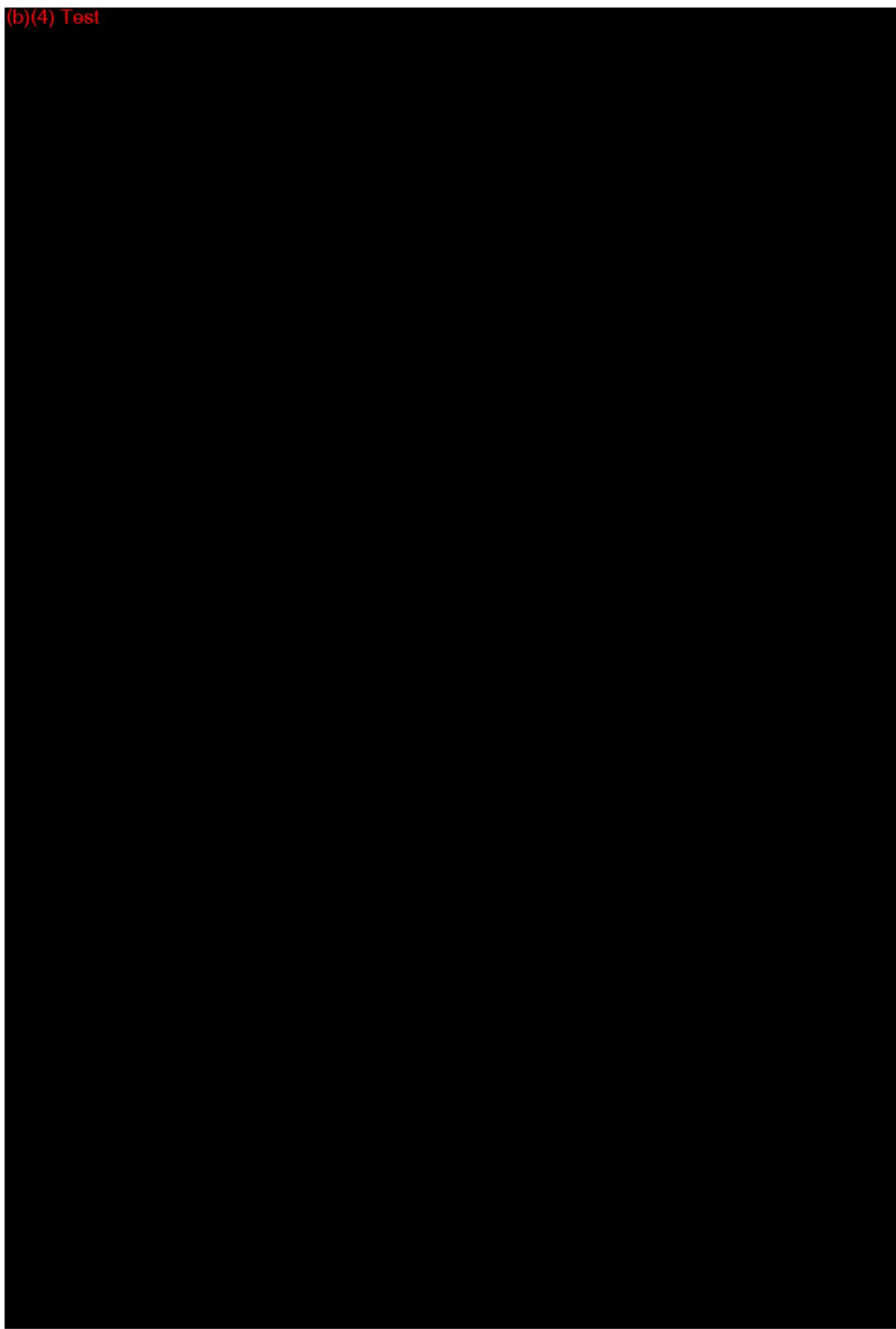


(b)(4)

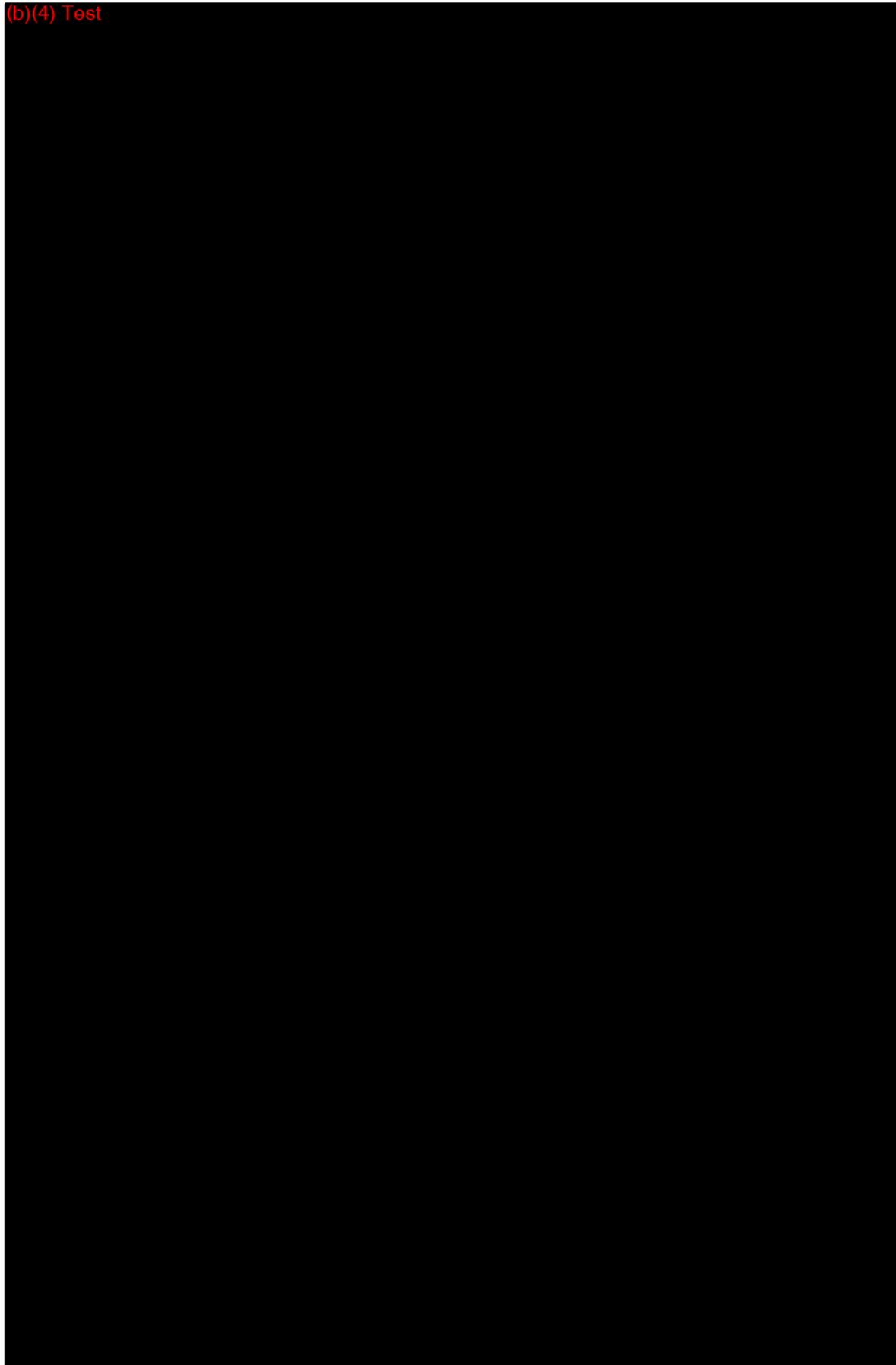


Prosurg Inc.  
Confidential

(b)(4) Test



(b)(4) Test









- (b) Tyvek / Mylar pouch Packaging Seal integrity did not get damaged, torn or compromised ( peel strength) during shelf life testing.
- (c) There were no holes, puncture or damage to Tyvek / Mylar pouch package ( dye check ) during shelf life testing .

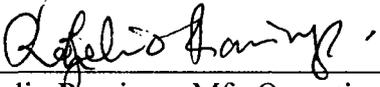
**11.0 RECOMMENDAED SHELF LIFE:**

Based on the result of Accelerated Ageing Test Method (ASTM F 1980: 2002) result, we have determined that Neoscope™ –Video Endoscope products have a minimum one (1) year shelf life from date of manufacturing. Please note that Product Sterility and Shelf life are in effect as long as the package is not opened or damaged.

Approved By:

  
\_\_\_\_\_  
Twila Conner QA

2/27/12  
\_\_\_\_\_  
Date

  
\_\_\_\_\_  
Rogelio Ramirez , Mfg Operation

2 - 27 - 12  
\_\_\_\_\_  
Date



































































July 10, 2012

To: Director, Food and Drug Administration.

Urology and Lithotripsy Devices Branch  
Division of Reproductive, Abdominal & Radiological Devices.  
Office of Device Evaluation / CDRH  
Document Mail Center (HFZ-401)  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-002

Re.: **510(k) Premarket Notification: # K120766**

***NeoScope™- Digital Video Endoscopic System***

Dear Sir,

Pursuant to 21 CFR 820.90, enclosed please find a copy of 510k Premarket Notification applications for the above named devices for your review.

The use of the term “substantially equivalent,” “similar” and other related terms and descriptions in this notification comparing *NeoScope™- Digital Video Endoscopy System* to the predicate devices are made only to meet the requirements of the Federal Food, Drug and Cosmetic Act as amended and regulations there under, and for no other purpose.

The NeoScope™- Digital Video Endoscopic System is substantially equivalent to the predicated devices ACMI Invisio ICN endoscopes, ACMI DUR Ureteroscope, Gyrus Invision Endoscopes and NeoScope™- Endoscopic Diagnostic & Treatment System from Prosurge Inc, cleared by FDA under 510k application K#042225, K # 060269, K#090814 and K# 042780 respectively. The only modification to the NeoScope Endoscopic System is to include the use of Digital endoscope device with CMOS sensor & LED module instead of a conventional “Rod lens” and “fiber optic” viewing endoscope and light source. As we all know, currently the CMOS / CCD Imaging sensor with LED represents a proven technology for endoscopic viewing and illumination of the target body organ. The Proposed NeoScope Video Endoscopic device ( Rigid & Flexible ) is designed to be compatible with commercial Laptop / Tablet computers . The NeoScope Video System is also designed for Single Use, thus minimizing risk of cross contamination and infections.

Please review the attached application and let us know if you need additional details or clarification.

Thank you and Best Regards,

A. Desai Manager, Regulatory Affairs

Prosurge

2195 Trade Zone Blvd

San Jose CA 95131

Tel 408 945 4044 / Fax 408 945 1390, E mail: Ashvin@Prosurge.com Inc

**510 (k) Application**

**NeoScope™- Digital Video Endoscopic System**

**Index**

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**510 (k) Notification**

Date: July 10, 2012

**Device Proprietary Name: NeoScope™- Digital Video Endoscopic System**

Device Common, Usual or Classification Name: Endoscope and Accessories Flexible / Rigid

Product Code: FAJ and FGA

Division /Subsidiary Name: Prosurg, Inc

Est. Regis No. 2939814

Notification for  New Device  Significant change/modification  Change in int. use

Classification Panel Name: Division of Reproductive, Abdominal & Radiological Devices / CDRH

Pursuant to 21 CFR Part 876 .1500 this device is:

Class I  Class II  Class III

Not Classified- the following provides the basis for this determination: N/A

Pursuant to Section S14 of the Act and 21 CFR part 861, the following action has been taken to assure performance to he appropriate performance standards:

Not Applicable  No standard(s) presently exist for this device

- The following performance standards apply and are being complied with: 21CFR Part 878.4300

The following is attached, where appropriate, in support of this 510k notification:

- Labels, labeling, advertisements, and/or directions
- Finished product photographs and engineering drawings
- Statement and data supportive of similarity/differences of comparable product types in distribution.

Supportive data in consideration of consequences and effects of a chance or modification as related to safety and effectiveness including a detailed description of the significant change/modification.

Supportive data in consideration of consequences and effects as related to a new use of the device including a detailed description of the new intended.

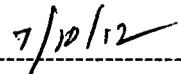
Confidentiality if intent to market:

Applicable

Not Applicable

Submitted by: A. Desai

Title:  Manager, Regulatory Affairs

  
Date

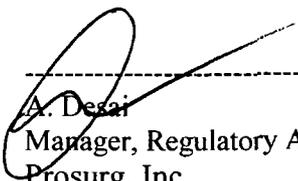
Prosurg, Inc  
2195 Trade Zone Blvd  
San Jose CA 95131

**Premarket Notification 510 (k) Statement  
(As required by 21 CFR 807.93)**

**NeoScope™- Digital Video Endoscopic System**

I certify that as Manager of Regulatory Affairs of Prosurg, Inc, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent.

The information I agree to make available will be duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade and confidential commercial information, as defined in 21 CFR 20.61.

  
-----  
A. Desai  
Manager, Regulatory Affairs  
Prosurg, Inc  
San Jose CA

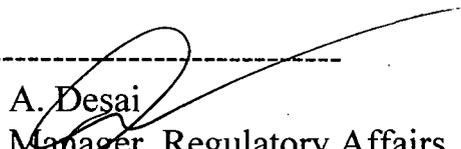
July 10, 2012

**Premarket Notification**

**Truthful and Accurate Statement**

***NeoScope*™- Digital Video Endoscopic System**

I certify that my capacity as Manager of Regulatory Affairs of Prosurg, Inc., I believe to the best of my knowledge that all data and information submitted in premarket notification are truthful and accurate and that no material fact has been omitted.

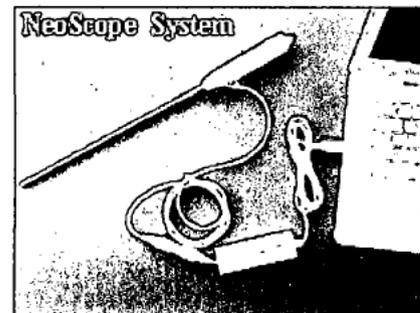
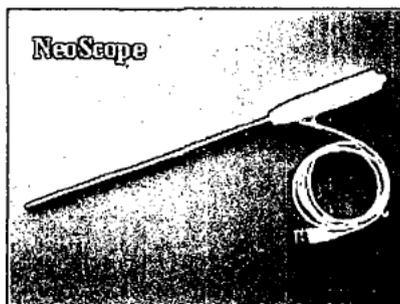
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A. Desai  
Manager, Regulatory Affairs  
Prosurg, Inc  
San Jose CA 95131

July 10, 2012

**Device Description: - NeoScope Cystoscope / Hysteroscope**

The NeoScope Video Endoscopic System consists of three main components:

- (a) Digital Video Endoscope ( Prosurg Inc )
- (b) Video Module & Software ( El Gato Company)
- (c) Laptop / Tablet Computer ( Mac, Windows Computer Companies)



**Digital Video Endoscope ( Rigid /Flexible)**

The Digital Video endoscope design incorporates a CMOS imaging sensor and 4 ea built-in LED ( Light Emitting Diodes) mounted at the distal end, connecting wires along the length of the hollow tubular structure and a USB 2.0 Connector at the proximal end. The distal end of the endoscope containing CMOS sensor and LEDs, is protected by sealed optical glass window and the proximal end of the tubular structure is housed into a medical grade ABS molded handle. The Neoscope endoscope is provided sterile for Single use only and does not require cleaning , reprocessing or re-sterilization. The Neoscope Endoscope is available as a 5.0mm OD diagnostic device or 7.5mm OD as an operating device with 5 Fr working channel. The Neoscope can be utilized as a Cystoscope or Hysteroscope by a trained physican for diagnostic and operating procedures, using commercially available, video capture module and portable laptop / Tablet computer.

**Video Capture Module & Software :**

The commercially available, Video Capture Module and Video Processing Software, commonly used to covert Analog video (VCR) tapes & other media into Digital files or DVD are supplied by (b)(4) company for use with majority of commercial computers. The Video Capture module with software are not patient contact items and can easily be connected / loaded to the Laptop/ Tablet computer. The Video Capture Module receives the analog signal from CMOS sensor of the endoscope and converts it into digital video signal recordings. The (b)(4) software is used to format the digital video recordings into commonly used video format files, including Quick Time, iTune, i Movie, window Media & You Tube.

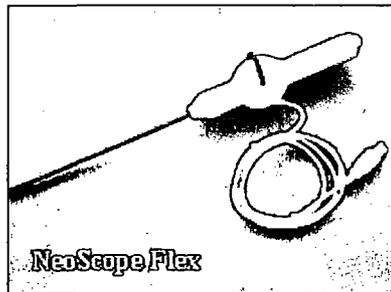
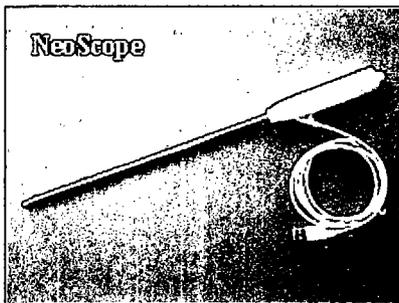
### **Portable Laptop / Tablet Computers:**

The Portable Laptop / Tablet Computer can be used as a video monitor and recording / storage device to view, record, edit, store and transfer /transmit the video files. The Digital Video Endoscope and Video Capture Module can be connected to majority of commercially available Laptop /Tablet computer using standard USB 2.0 connecting cables. If necessary, additional USB connecting cable can also be used.

- Note: The Laptop / Tablet Computer is commercially available product (Mac or Windows based Operating System) (Not supplied by Prosurg, Inc)

## NeoScope Product Configurations : ( Rigid / Flexible)

**Neo -Cystoscopes / Neo- Hysteroscope for Diagnosis and treatment of Urological disorders and Gynecological disorders.**



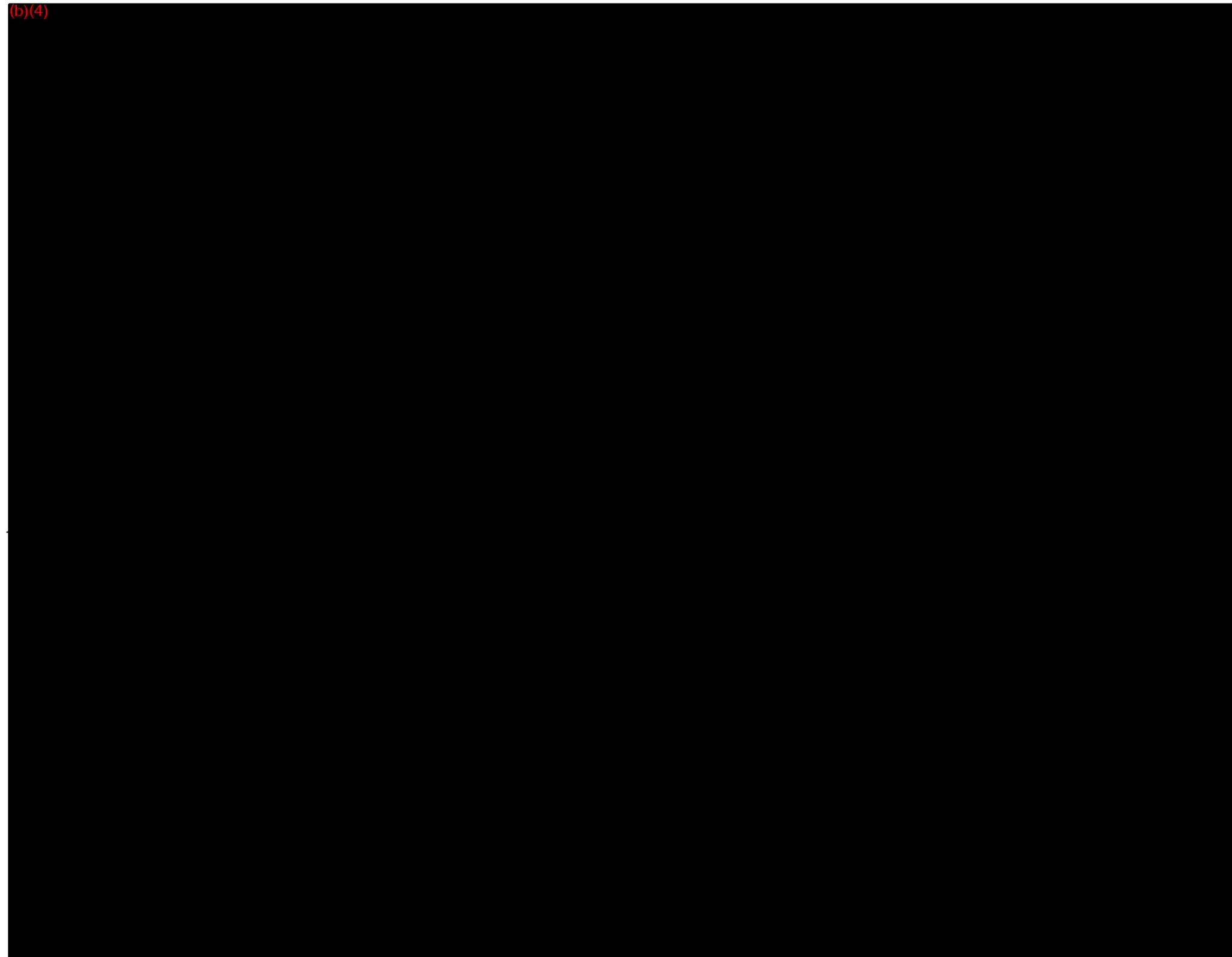
### NeoScope Product Models :

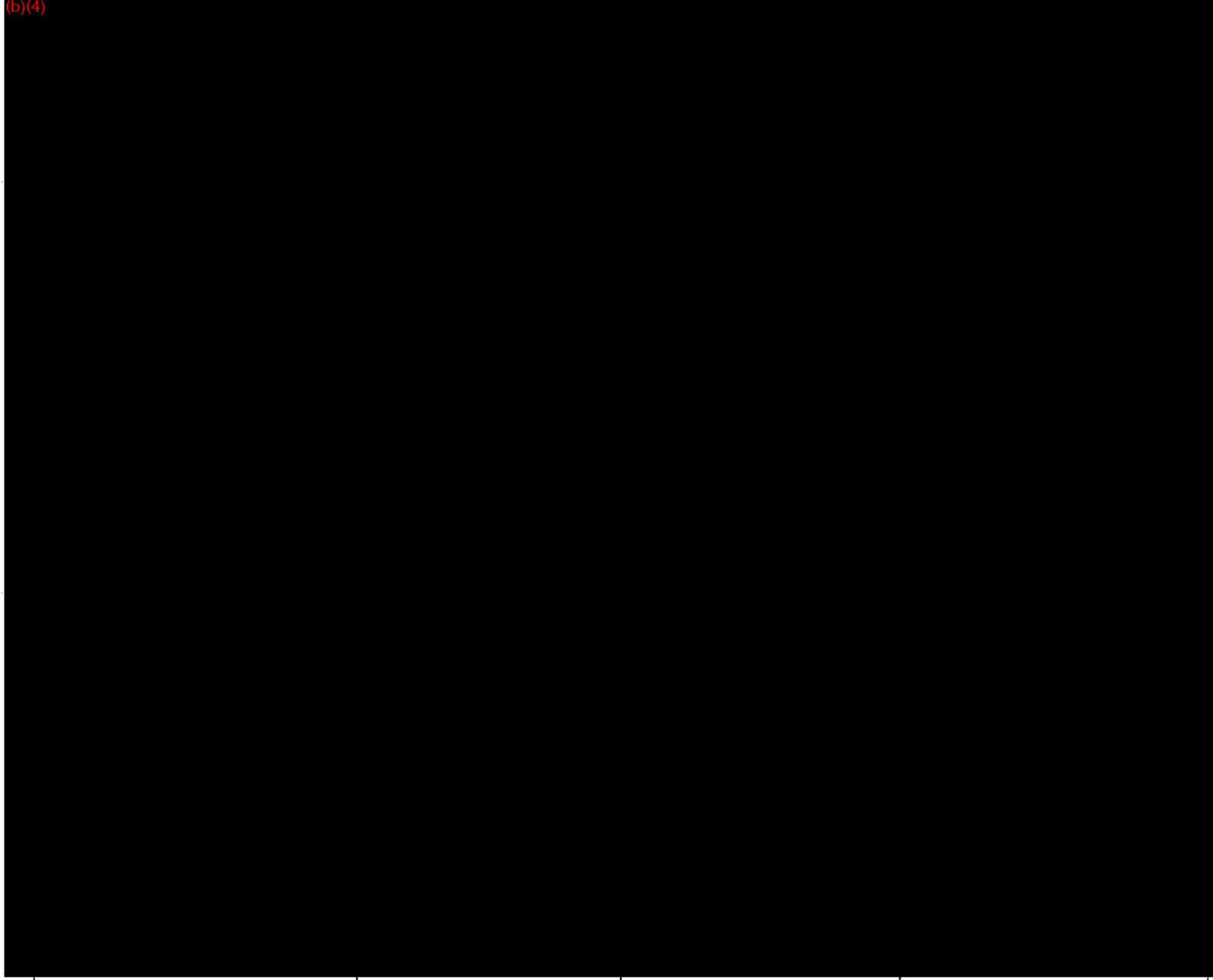
NeoScope -Digital Video Cystoscopes & Hysteroscopes ( Rigid / Flexible)

#### Model #

#### Product Description

NCR50S	Diagnostic Neo-Cystoscope	(5.0mm Dia, 28 cm long)
NCR75S	Operating Neo-Cystoscope	(7.5mm Dia, 28 cm long)
NHR50S	Diagnostic Neo-Hysteroscope	(5.0mm Dia, 28 cm long)
NHR75S	Operating Neo-Hysteroscope	(7.5mm Dia, 28 cm long)
NCF75S	Operating NeoFlex-Cystoscope	(7.5mm Dia, 36 cm long)
NHF75S	Operating NeoFlex-Hysteroscope	(7.5mm Dia, 36 cm long)
NVMM	Video Module & Software (Mac)	
VMW	Video Module & Software (Windows)	
USB60	USB 2.0 Connecting cable 6.0ft	
USB12	USB 2.0 Connecting cable 12.0ft	





(b)(4)

**Product Specifications:**

**NeoScope™- Digital Video Endoscopic System**

**(i) Digital Video Endoscope ( Rigid ) :**

Endoscope Diameter : 5.0 mm , 7.5mm  
Endoscope Length: 28cm  
Endoscope Working Channel: 5 Fr

**(ii) Digital Endoscope ( Flexible ) :**

Endoscope Diameter : 7.5 mm ,  
Endoscope Length: 38 cm  
Endoscope Working Channel: 5 Fr

**(iii) Accessories: ( Video Module & Connecting cable (Non patient contact items)**

Video Module: Commercially available, El Gato video module ( Windows / Mac OS)  
Connecting Cable : Commercially available standard cable with USB 2.0 connector  
Video Display Monitor : Commercially available Laptop/ Tablet Computer / Mobile phone

**(iv) Digital Video Endoscope Material Specifications:**

**(a) Digital Video Endoscope :**

Video Endoscope outer Sheath ( Rigid ) : S.S. 304 /316  
Flexible Endoscope outer Sheath : TFE  
Optical window : Glass (Quartz)  
Endoscope Handle: Medical grade ABS Polymer ( Molded )

**(b) Packaging:** Tyvek / Mylar Pouch

## **Material Biocompatibility**

### **NeoScope™- Digital Video endoscopic System**

The materials used for manufacturing and packaging of NeoScope™- Digital Video endoscopic System are identical to predicate device and are safe and biocompatible materials, that are widely used in the medical industry.

NeoScope™- Digital Video endoscope Devices are made from stainless Steel 304 /306 tubing covered and Medical Grade ABS molded handle. Neoscope – Video System is identical in materials, manufacturing methods , assembly, packaging and sterilization as predicated device. The endoscopic devices are made from stainless steel (304 / 306) with medical grade ABS polymer handle.. All of the materials have long established history of biocompatibility and use in medical devices. The packaging materials including Tyvek/ Mylar pouch is also identical to the predicate device. The packaging materials are not patient contact items and are not utilized in the medical procedures. The Video module and video display monitors are commercially available and are also non patient contact items.

The Biocompatibility Report for the NeoScope Diagnostic and Therapeutic Endoscopic System , as per limited Contact device ( less than 24 hours ) according to ISO 10993 standards has been attached herewith for your review. Please note that the Biocompatibility report includes Cytotoxicity study, ISO intracutaneous study and ISO maximization and Sensitization study for the Neoscope Diagnostic and Therapeutic Endoscopic System. Please note that the material, packaging manufacturing process, sterilization method & cycle are also identical. The Video module and laptop / Tablet computer being, not patient contact items are provided non sterile.

## **Product Sterilization**

### **NeoScope™- Digital Video Endoscopic System**

*NeoScope™*- Digital Video Endoscope will be provided sterile, for single use only. The endoscope have been sterilized using Ethylene Oxide gas by an outside contractor, Steris, Inc. The ETO sterilization protocol has been validated for sterility assurance level of  $10^{-6}$ . Following each of these cycles, inoculated products have been tested for sterility. In addition, following each full cycle, the product samples have been tested for residual level of ETO, ETCH, and EGLY and found to be well within FDA / ISO guidelines

The Video Module and video display monitors are commercially available items and will be supplied Non Sterile, being a non patient contact items.

#### Product Sterilization & Residual Gas levels:

The Gas Residual levels for the proposed device, with contact for limited exposure devices, does not exceed the following guideline levels, as proposed in ANSI /AAMI /ISO 10993-7: - 2008 – Biological Evaluation of Medical Devices- Part 7 “Ethylene Oxide Sterilization Residuals”

The Guidelines for residual Gas limits for Medical devices for Limited Exposure are:

Ethylene Oxide (EO) – not to exceed 20 mg per day,

Ethylene Chlorohydrin (ECH)- not to exceed 12mg in a day

The actual value of residual ETO, ECH gas level (5 days post Sterilization) were  $\leq 0.3$  mg / sample and  $\leq 1$  mg / sample respectively. The residual gas value for the device is well within the proposed FDA/ISO guidelines limits.

The product sterilization challenge has been conducted for sterility assurance for level  $10^{-6}$  using cycles using 100% ETO. The product sterility testing is based on LAL testing using BI spores. The sterilization validation is based on ANSI/AAMI / ISO 11135-1: 2007 and EN 550: 1994 guidelines for ETO sterilization

## Indications for Use

510(k) Number (if known): #K120766

Device Name: **NeoScope™ Digital Video Endoscopic System**

Indications For Use:

The Prosurg's NeoScope (Cystourethroscope /Cystoureteroscope /Cystonephroscope) Digital Video System (which includes the Digital video Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Urinary tract, and can be percutaneously to examine the interior of the kidney and using additional accessories can be used to perform various diagnostic and therapeutic procedures.

The Prosurg's Neoscope (Hysteroscope) Digital Video System (which includes the Digital Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Gynecological tract, and can be percutaneously to examine the interior of the uterus and using additional accessories can be used to perform various diagnostic and therapeutic procedures.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of \_\_\_\_\_

**Indications for Use:**

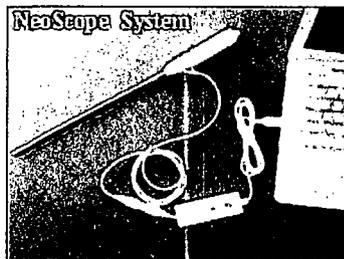
**NeoScope™- Digital Video Endoscopic System**

The Prosurg's NeoScope (Cystourethroscope /Cystoureteroscope /Cystonephroscope) Digital Video System (which includes the Digital video Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Urinary tract, and can be percutaneously to examine the interior of the kidney and using additional accessories can be used to perform various diagnostic and therapeutic procedures.

The Prosurg's Neoscope (Hysteroscope) Digital Video System (which includes the Digital Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Gynecological tract, and can be percutaneously to examine the interior of the uterus and using additional accessories can be used to perform various diagnostic and therapeutic procedures.

## Product Labeling

### **NeoScope™- Digital Video Endoscopic System ( Diagnostic – Neo-Cystoscope )**



**Model # NCR 50**

**Qty: 1 ea**

**Endoscope Size: 5.0mm ( Dia )**

**Length : \_28cm**

**Suction / Irrigation : Yes**

**Working Channel : No**

**Video Module : ( Mac / Windows)**

**Date Of mfg: \_\_\_\_\_**

**Exp. Date : \_\_\_\_\_**

**Sterilization Method : ETO Gas**

**For Single use only**

Contents sterile unless package is damaged or open.

**Caution:** Federal (USA) law restricts this device to use by or on the order of a physician  
Please refer to Instructions for Use for additional information, & Guidelines

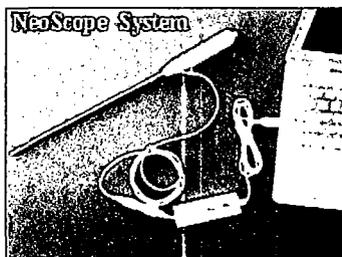
Lot # -----

P/N # ----- Rev ----

**Prosurg, Inc**  
2193 Trade Zone Blvd  
San Jose CA 95131  
Tel: 408 945 4040

### Product Labeling

#### **NeoScope™- Digital Video Endoscopic System ( Diagnostic – Neo-Hysteroscope )**



**Model # NHR 50**

**Qty: 1 ea**

**Endoscope Size: 5.0mm ( Dia )**

**Length : -28cm**

**Suction / Irrigation : Yes**

**Working Channel : No**

**Video Module : ( Mac / windows)**

**Date Of mfg: \_\_\_\_\_**

**Exp. Date : \_\_\_\_\_**

**Sterilization Method : ETO Gas**

**For Single use only**

Contents sterile unless package is damaged or open.

**Caution:** Federal (USA) law restricts this device to use by or on the order of a physician  
Please refer to Instructions for Use for additional information, & Guidelines

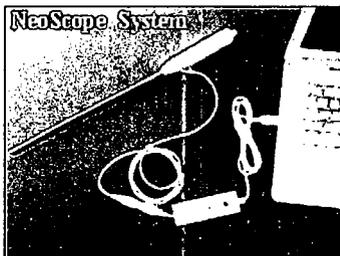
Lot # -----

P/N # ----- Rev ----

**Prosurg, Inc**  
2193 Trade Zone Blvd  
San Jose CA 95131  
Tel: 408 945 4040

### Product Labeling

#### **NeoScope™- Digital Video Endoscopic System ( Operating – Neo Cystoscope )**



**Model #** NCR 75

**Qty:** 1 ea

**Endoscope Size:** 7.5mm ( Dia )

**Length :** 28cm

**Suction / Irrigation :** Yes

**Working Channel :** 5 Fr

**Video Module :** ( Mac / Windows)

**Date Of mfg:** \_\_\_\_\_

**Exp. Date :** \_\_\_\_\_

**Sterilization Method :** ETO Gas

**For Single use only**

Contents sterile unless package is damaged or open.

**Caution:** Federal (USA) law restricts this device to use by or on the order of a physician  
Please refer to Instructions for Use for additional information, & Guidelines

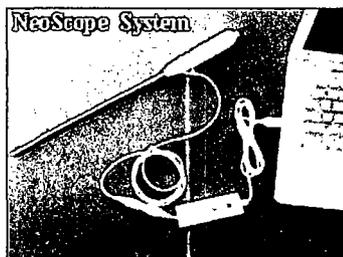
Lot # -----

P/N # ----- Rev ----

**Prosurg, Inc**  
2193 Trade Zone Blvd  
San Jose CA 95131  
Tel: 408 945 4040

### Product Labeling

#### **NeoScope™- Digital Video Endoscopic System ( Operating – Neo-Hysteroscope )**



**Model #** NHR 75

**Qty:** 1 ea

**Endoscope Size:** 7.5 mm ( Dia )

**Length :** 28cm

**Suction / Irrigation :** Yes

**Working Channel :** 5 Fr

**Video Module :** ( Mac / Windows)

**Date Of mfg:** \_\_\_\_\_

**Exp. Date :** \_\_\_\_\_

**Sterilization Method :** ETO Gas

**For Single use only**

Contents sterile unless package is damaged or open.

**Caution:** Federal (USA) law restricts this device to use by or on the order of a physician  
Please refer to Instructions for Use for additional information, & Guidelines

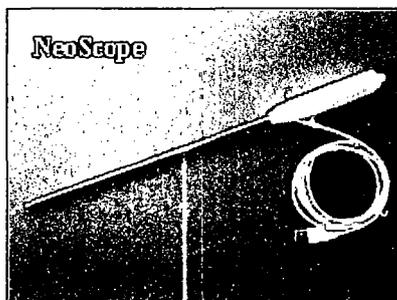
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P/N # ----- Rev ----

**Prosurg, Inc**  
2193 Trade Zone Blvd  
San Jose CA 95131  
Tel: 408 945 4040

**Product Labeling**

**NeoScope™- Digital Video Endoscope  
( Diagnostic – Neo-Cystoscope )**



**Model #** NCR 50S

**Qty:** 1 ea

**Endoscope Size:** 5.0 mm ( Dia )

**Length :** 28cm

**Suction / Irrigation :** Yes

**Working Channel :** No

**Date Of mfg:** \_\_\_\_\_

**Exp. Date :** \_\_\_\_\_

**Sterilization Method :** ETO Gas

**For Single use only**

Contents sterile unless package is damaged or open.

**Caution:** Federal (USA) law restricts this device to use by or on the order of a physician  
Please refer to Instructions for Use for additional information, & Guidelines

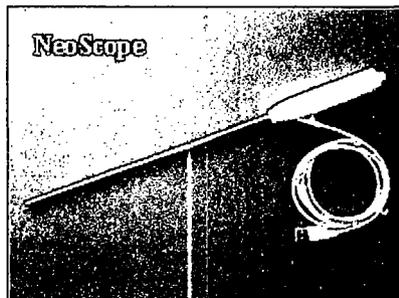
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P/N # ----- Rev ----

**Prosurg, Inc**  
2193 Trade Zone Blvd  
San Jose CA 95131  
Tel: 408 945 4040

**Product Labeling**

**NeoScope™- Digital Video Endoscope  
( Diagnostic – Neo-Hysteroscope )**



**Model # NHR 50S**

**Qty: 1 ea**

**Endoscope Size: 5.0 mm ( Dia )**

**Length : 28cm**

**Suction / Irrigation : Yes**

**Working Channel : No**

**Date Of mfg: \_\_\_\_\_**

**Exp. Date : \_\_\_\_\_**

**Sterilization Method : ETO Gas**

**For Single use only**

Contents sterile unless package is damaged or open.

**Caution:** Federal (USA) law restricts this device to use by or on the order of a physician  
Please refer to Instructions for Use for additional information, & Guidelines

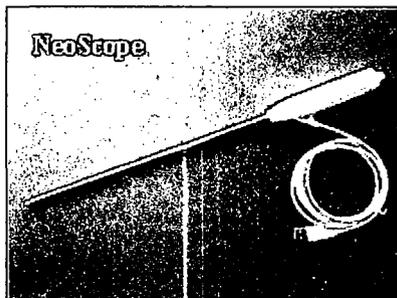
Lot # -----

P/N # ----- Rev ----

**Prosurg, Inc**  
2193 Trade Zone Blvd  
San Jose CA 95131  
Tel: 408 945 4040

**Product Labeling**

**NeoScope™- Digital Video Endoscope  
( Operating – Neo-Cystoscope )**



**Model # NCR 75S**

**Qty: 1 ea**

**Endoscope Size: 7.5 mm ( Dia )**

**Length : 28cm**

**Suction / Irrigation : Yes**

**Working Channel : 5 Fr**

**Date Of mfg: \_\_\_\_\_**

**Exp. Date : \_\_\_\_\_**

**Sterilization Method : ETO Gas**

**For Single use only**

Contents sterile unless package is damaged or open.

**Caution:** Federal (USA) law restricts this device to use by or on the order of a physician  
Please refer to Instructions for Use for additional information, & Guidelines

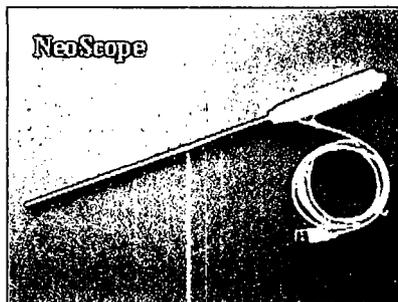
Lot # -----

P/N # ----- Rev ----

**Prosurg, Inc**  
2193 Trade Zone Blvd  
San Jose CA 95131  
Tel: 408 945 4040

**Product Labeling**

**NeoScope™- Digital Video Endoscope  
( Operating – Neo-Hysteroscope )**



**Model #** NHR 75S

**Qty:** 1 ea

**Endoscope Size:** 7.5 mm ( Dia )

**Length :** 28cm

**Suction / Irrigation :** Yes

**Working Channel :** 5 Fr

**Date Of mfg:** \_\_\_\_\_

**Exp. Date :** \_\_\_\_\_

**Sterilization Method :** ETO Gas

**For Single use only**

Contents sterile unless package is damaged or open.

**Caution:** Federal (USA) law restricts this device to use by or on the order of a physician  
Please refer to Instructions for Use for additional information, & Guidelines

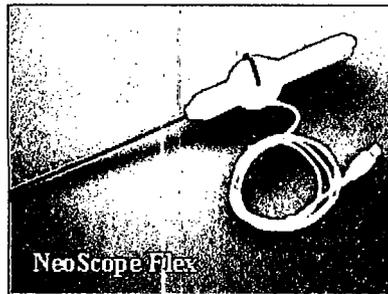
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P/N # ----- Rev ----

**Prosurg, Inc**  
2193 Trade Zone Blvd  
San Jose CA 95131  
Tel: 408 945 4040

**Product Labeling**

**NeoScope™- Digital Video Flexible Endoscope  
( Operating – NeoFlex-Cystoscope )**



**Model #** NCF 75S

**Qty:** 1 ea

**Endoscope Size:** 7.5 mm ( Dia )

**Length :** 36 cm

**Suction / Irrigation :** Yes

**Working Channel :** 5 Fr

**Date Of mfg:** \_\_\_\_\_

**Exp. Date :** \_\_\_\_\_

**Sterilization Method :** ETO Gas

**For Single use only**

Contents sterile unless package is damaged or open.

**Caution:** Federal (USA) law restricts this device to use by or on the order of a physician  
Please refer to Instructions for Use for additional information, & Guidelines

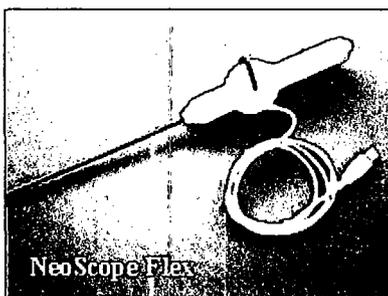
Lot # -----

P/N # ----- Rev ----

**Prosurg, Inc**  
2193 Trade Zone Blvd  
San Jose CA 95131  
Tel: 408 945 4040

**Product Labeling**

**NeoScope™- Digital Video Flexible Endoscope  
( Operating – NeoFlex-Hysteroscope )**



**Model # NHF 75S**

**Qty: 1 ea**

**Endoscope Size: 7.5 mm ( Dia )**

**Length : 36 cm**

**Suction / Irrigation : Yes**

**Working Channel : 5 Fr**

**Date Of mfg: \_\_\_\_\_**

**Exp. Date : \_\_\_\_\_**

**Sterilization Method : ETO Gas**

**For Single use only**

Contents sterile unless package is damaged or open.

**Caution:** Federal (USA) law restricts this device to use by or on the order of a physician  
Please refer to Instructions for Use for additional information, & Guidelines

Lot # -----

P/N # ----- Rev ----

**Prosurg, Inc**  
2193 Trade Zone Blvd  
San Jose CA 95131  
Tel: 408 945 4040

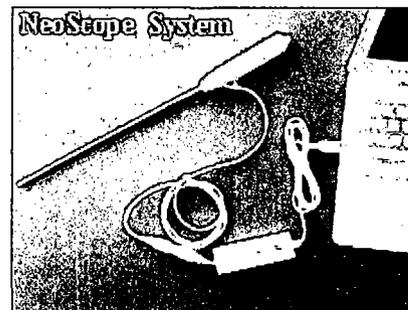
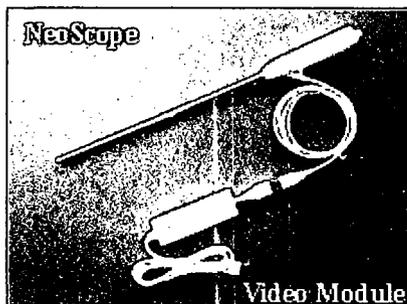
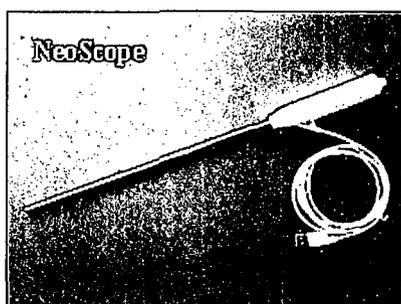
## Instruction for Use

### NeoScope™- Digital Video Endoscopic System

#### Device Description: - NeoScope Cystoscope / Hysteroscope

The NeoScope Video Endoscopic System consists of three main components:

- (a) Digital Video Endoscope ( Prosurg Inc )
- (b) Video Module & Software ( El Gato Company)
- (c) Laptop / Tablet Computer ( Mac , Window Computer Companies)



#### **Digital Video Endoscope ( Rigid /Flexible)**

The Digital Video endoscope design incorporates a CMOS imaging sensor and 4 ea built-in LED ( Light Emitting Diodes) mounted at the distal end, connecting wires along the length of the hollow tubular structure and a USB 2.0 Connector at the proximal end. The distal end of the endoscope containing CMOS sensor and LEDs, is protected by sealed optical glass window and the proximal end of the tubular structure is housed into a medical grade ABS molded handle. The Neoscope endoscope is provided sterile for Single use only and does not require cleaning , reprocessing or re-sterilization. The Neoscope Endoscope is available as a 5.0mm OD diagnostic device or 7.5mm OD as an operating device with 5 Fr working channel. The Neoscope can be utilized as a Cystoscope or Hysteroscope by a trained physican for diagnostic and operating procedures, using commercially available, video capture module and portable laptop / Tablet computer.

#### **Video Capture Module & Software :**

The commercially available, Video Capture Module and Video Processing Software, commonly used to covert Analog video (VCR) tapes & other media into Digital files or DVD are supplied by El Gato company for use with majority of commercial computers. The Video Capture module with software are not patient contact items and can easily be connected / loaded to the Laptop/ Tablet computer. The Video Capture Module receives the analog signal from CMOS sensor of the endoscope and converts it into digital video signal recordings. The El Gato software is used to format the digital video recordings into commonly used video format files, including Quick Time, iTune, i Movie, window Media & You Tube.

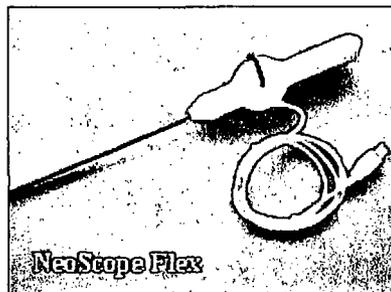
### Portable Laptop / Tablet Computers:

The Portable Laptop / Tablet Computer can be used as a video monitor and recording / storage device to view, record, edit, store and transfer /transmit the video files. The Digital Video Endoscope and Video Capture Module can be connected to majority of commercially available Laptop /Tablet computer using standard USB 2.0 connecting cables. If necessary, additional USB connecting cable can also be used.

- Note: The Laptop / Tablet Computer is commercially available product (Mac or Window based Operating System) (Not supplied by Prosurg, Inc)

### NeoScope Product Configurations : ( Rigid / Flexible)

Neo -Cystoscopes / Neo- Hysteroscope for Diagnosis and treatment of Urological disorders and Gynecological disorders.



### NeoScope Product Models :

NeoScope -Digital Video Cystoscopes & Hysteroscopes ( Rigid / Flexible)

Model #	Product Description
NCR50S	Diagnostic Neo-Cystoscope (5.0mm Dia, 28 cm long)
NCR75S	Operating Neo-Cystoscope (7.5mm Dia, 28 cm long)
NHR50S	Diagnostic Neo-Hysteroscope (5.0mm Dia, 28 cm long)
NHR75S	Operating Neo-Hysteroscope (7.5mm Dia, 28 cm long)
NCF75S	Operating NeoFlex-Cystoscope (7.5mm Dia, 36 cm long)
NHF75S	Operating NeoFlex-Hysteroscope (7.5mm Dia, 36 cm long)
NVMM	Video Module & Software (Mac)
VMW	Video Module & Software (Windows)
USB60	USB 2.0 Connecting cable 6.0ft
USB12	USB 2.0 Connecting cable 12.0ft

## **(2) Indications For Use:**

The Prosurge's NeoScope ( Cystourethroscope/ Cystourethroscope/ Cystonephroscope) Digital Video System (which includes the Digital video Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Urinary tract, and can be percutaneously to examine the interior of the kidney and using additional accessories can be used to perform various diagnostic and therapeutic procedures.

The Prosurge's Neoscope (Hysteroscope) Digital Video System (which includes the Digital Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Gynecological tract, and can be percutaneously to examine the interior of the uterus and using additional accessories can be used to perform various diagnostic and therapeutic procedures.

## **Contraindications:**

The NeoScope Video endoscope for Cystourethroscopy is contraindicated for patients with Urinary Tract Infection ( UTIs).

The NeoScope Video endoscope for Hysteroscope is contraindicated for patients with current or recent pelvic infection, vaginitis, cervicitis, uterine perforation, uterine cancer and pregnancy.

## **Warnings:**

The NeoScope –Digital Video Endoscopic System is intended for use by trained physicians only. The device should not be used until the physician is familiar with the instructions for use, assembly and care of the device. Device instruction manual should be carefully studied and be available to the surgical / endoscopic team during the procedure. It is essential to follow the instructions contained in the instruction manual pertaining to the devices used in the procedure, with particular attention given to the warnings and cautions. Care must be exercised during endoscopic procedure or the video endoscope may create perforation, infection or damage to the endoscope .Care must be exercised during endoscopic insertion so as to avoid damage or injury to the surrounding tissue. Possible injuries may include unintended tissue damage beyond the zone of target tissue, compromised vasculature, injury to underlying organs or surrounding tissue not targeted for the treatment. Endoscopic visualization or other imaging diagnosis must be performed during the procedure to verify that there is no potential damage to the other tissue structure or body organs. After the endoscopic

procedure, the patient should be counseled for potential side effects and emergency instructions.

Video endoscope is supplied Sterile using an ethylene oxide (ETO) process. Do not use, if sterile barrier is damaged. If damage is found, please DO NOT USE. For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

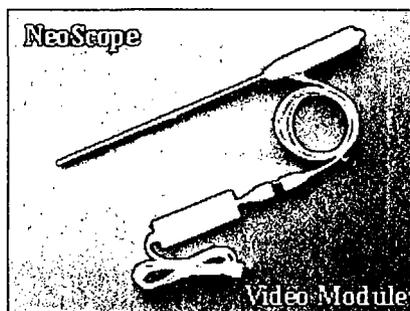
- **Cautions:**

- Recommended for Single (one time) use only.
- Bending or kinking during or prior to placement could damage integrity of the endoscope.
- If resistance is encountered during advancement or withdrawal of the microsurgical instrumentation into working channel of the Video endoscope, STOP. Do not continue without first determining the cause of the resistance and taking remedial action..

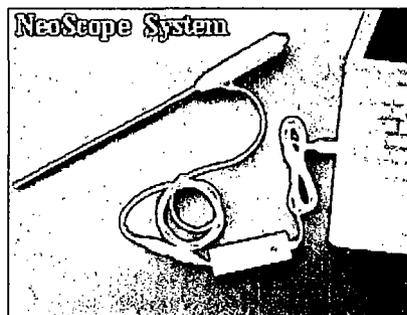
*Federal (USA) law and governing law outside the USA restrict these devices to sale by or on the order of a physician.*

**(3) Inspection and Assembly:**

3.1 Use aseptic technique when removing the NeoScope™ Digital Video Endoscope from the package. Prior to use, carefully inspect the device for any visible signs of damage. DO NOT USE the device if it appears to be cracked, flawed, or otherwise damaged. DO NOT BEND OR MANIPULATE THE DEVICE.



Video Endoscope & Video Module



Video Endoscope, Video Module & Monitor

3.2 Carefully remove the Video module from the Package. Prior to use, carefully inspect the device for any visible signs of damage. **DO NOT USE** the device if it appears to be cracked, flawed, or otherwise damaged. Remove the El Gato software disc from the package, install and launch the appropriate version of software on Mac / Window laptop / tablet computer. Optionally, the software can also be downloaded from El Gato website ( [www. Elgato.com](http://www.Elgato.com)).

3.3 Connect the Video module with USB connector to Laptop / Tablet computer. Use a male / female USB extension cord , if necessary to provide additional length between laptop / tablet computer and Video endoscope.

3.4 Using aseptic technique in sterile field, connect the video endoscope to video module, using male/ female USB 2.0 connector.

3.5 Launch El Gato application on the laptop / tablet computer and follow the on screen instructions to record, edit, store and format the video recording of the procedure. Transfer or transmit the video recording to patient file or other device.

#### **(4) Diagnostic & Surgical Procedure:**

4.1, The NeoScope Video endoscopic system can be used for various endoscopic procedure for treatment of Urological, Uro-gynecological or Gynecological disorders, using appropriate model of Video endoscope.

4.4 Prepare the patient and operating work area. Select the appropriate model of NeoCystoscope or NeoHysteroscope for diagnostic or therapeutic procedure. Attach irrigation / aspiration tubing using lure lock connection mounted on the proximal end of the video endoscope handle. Make sure the lure lock connection is secure. The working channel of the operating Video Endoscope model including NeoCystoscope , NeoHysteroscope , NeoFlex Cysoscope and NeoFlex Hysteroscope can be used for suction / irrigation of fluid and 5 Fr microsurgical instruments for various Cystoscopic and Hysteroscopic procedures.

#### **5. STERILIZATION:**

The NeoScope™- Digital Video endoscope is provided in sterile packaging and is intended for single use only. Do not use if the product sterility is compromised due to damaged package. It is recommended that product be stored in a cool dry storage facility. The NeoScope™ video endoscope and packaging should be properly disposed of at the end of the procedure according to hospital/clinic policy. Do not attempt to re-sterilize

#### **6 GENERAL WARNING:**

The The NeoScope™- Digital Video Endoscopic System is intended for use only by physicians. The user of the device should be thoroughly trained in its use and the

applicable medical procedures. Use of these devices should no be undertaken until the user has fully familiarized himself with the instructions for use, assembly and care. Equipment instruction manuals should have been carefully studied and be available to the surgical team during the procedure. It is essential to follow the instructions contained in instruction manual pertaining to devices used in the procedure, with particular attention given to the warnings and cautions. Care must be exercised during surgical procedure, or the instrument may potentially create perforation, infection, device damage or breakage. After the surgical procedure, the patient should be counseled for potential side effects, if any and emergency instructions.

**\*\*\*\*\* LIMITED WARRANTY\*\*\*\*\***

Prosurg, Inc warrants the NeoScope™- Digital Video Endoscopic System to be free from defects in material and workmanship for a period of 30 days from the day of shipment when properly installed, maintained, and used for its intended purpose. This warranty applies only to the original purchaser, and only so long as the equipment is used in the country to which Prosurg, Inc originally shipped it. This warranty is null and void if the user attempts to reuse, resterilize, or modify the device in any way. If after examination by Prosurg's Service Representative, any portion of the product is found to be defective within the period described above, and Prosurg, Inc is satisfied that the failure was due to defective materials and /or workmanship, Prosurg will, at its option, replace the defective product without charge.

THIS EXPRESS WARRANTY ABOVE IS THE SOLE WARRANTY OF OBLIGATION OF PROSURG, INC AND THE REDEMY PROVIDED ABOVE IS IN LIEU OF ANY AND ALL OTHER REDEMIES.THERE ARE NO OTHER AGREEMENTS, GUARANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. PROSURG, INC SHALL HAVE NO LIABILITY WHATSOEVER FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGE ARISING OUT OF ANY DEFECT, IMPROPER USE, OR UNAUTHORIZATION SERVICE OR REPAIR.

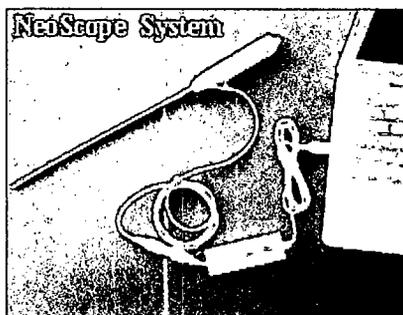
Prior to the return of the product, or any portion thereof, the Prosurg, Inc representative must be consulted. If return of the device/ instrument is deem necessary, a Returned Material Authorization number will be assigned. This number must be recorded on the outside of the shipping container and on the return packing list. Please contact:

Customer Service Dept.  
Prosurg, Inc (www.Prosurg.com)  
2193 Trade Zone Blvd.  
San Jose, CA 95131 U.S.A  
Tel.: (408) 945-4044`

July 10, 2012

### **Substantially Equivalent Information**

#### **NeoScope™- Digital Video Endoscopic System**



The NeoScope™- Digital Video Endoscopic System is substantially equivalent to the predicated devices ACMI INVISIO ICN Endoscope, ACMI DUR –Digital Ureteroscope, Gyrus ACMI Invisio ICN Endoscope and NeoScope™- Endoscopic Diagnostic & Treatment System from Prosurge Inc, cleared by FDA under 510k application K# 042225, K#060269, K# 090814 and K# 042780 respectively. The only modification to the NeoScope Endoscopic System is to include the use of Digital endoscope device with CMOS sensor & LED module instead of a conventional “Rod lens” or “fiber optics” viewing endoscope and light source. The FDA regulatory clearance report, 510k application and product information details regarding predicated device is attached herewith for your review and consideration. Please review the comparison matrix outlining the Product specifications, Material compatibility and Indications for Use for the proposed device with predicated device. Please note that the proposed product is substantially equivalent to predicated devices in product design, materials, packaging and its intended use.

July 10, 2012

**Substantially Equivalent Information ( Revised)****NeoScope™- Digital Video Endoscopic System**

<b>Company</b>	<b>ACMI Corporation</b>	<b>ACMI Corporation</b>	<b>Gyrus /ACMI Corporation</b>	<b>Prosurg, Inc</b>	<b>Prosurg Inc</b>
<b>Product Name</b>	ACMI INVISIO ICN Digital Cysto Nephroscope	ACMI DUR System Digital Uretroscope	Gyrus /ACMI INVISIO ICN Digital Cysto Nephroscope	NeoScope™- - Endoscopic Diagnostic & Treatment System	NeoScope™- - Endoscopic Diagnostic & Treatment System (Modification)
<b>510(k)</b>	<b>K042225</b>	<b>K060269</b>	<b>K090814</b>	<b>K042780</b>	<b>K120766</b>
<b>Product Specifications:</b>					
Camera Sensor	CMOS	CMOS	CMOS	Rod Lense	CMOS
Light Sorce	Built-in LEDs	Built-in LEDs	Built-in LEDs	Xenon Light	Built-in LEDs
Video Processing	PCB & Software	PCB & Software	PCB & Software	PCB	PCB & Software
Endoscope Type	Flexible	Flexible	Flexible	Rigid	Rigid / Flexible
<b>Dimensions:</b>					
Endoscope Diameter: ( mm )	5.0mm	15 Fr ( 5.0mm)	5.0mm	4.5 mm	5.0mm ,& 7.5mm
Endoscope Length ( cm )	37 cm	100cm	37 cm	35 cm	38 cm
Viewing Angle ( degree)	zero degree	zero degree	zero degree	Zero & 30 degree	zero degree
<b>Recommended Usage of Endoscope</b>	Reusable	Reusable	Reusable	Reusable	Single Use Only Supplied Sterile

July 10, 2012

**Substantially Equivalent Information.**

**NeoScope™- Digital Video Endoscopic System**

Product Name	Company	510(k)	Indication for Use
MI INVISIO ICN Digital Cysto Nephroscope	<b>ACMI Corporation</b>	K042225	The ACMI INVISIO ICN (ICN) Digital Flexible Cysto Nephroscope System( which includes ICN scope & Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney and using additional accessories, can be used to perform various diagnostic and therapeutic procedures
ACMI DUR System Digital Uretroscope	<b>ACMI Corporation</b>	K060269	The ACMI DUR –Digital Uretroscope and Choledochoscope( DUR-D) System ( which includes the DUR- Digital Invisio Flexible Uretroscope and Choledochoscope and IDC Invisio Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract and can be used percutaneously to examine the interior of the kidney and using additional accessories, can be used to perform various diagnostic and therapeutic procedures. The DUR –D system is also indicated for the examination of bile ducts and using additional accessories to perform various diagnostic and therapeutic procedures during cholecystectomy.
Gyrus /ACMI INVISIO ICN Digital Cysto Nephroscope	<b>Gyrus /ACMI Corporation</b>	K090814	The Gyrus ACMI Invisio ICN ( CystoNephroscope) System (which includes the ICN Endoscope and Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be percutaneously to examine the interior of the kidney and using additional accessories can be used to perform various diagnostic and therapeutic procedures.
Scope™- - Endoscopic Diagnostic & Treatment System	<b>Prosurg, Inc</b>	K042780	NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification ) is intended for Cystoscopic, Hysteroscopic, Laparoscopic , Resectoscopic and Endoscopic treatment of Urological, Gynecological, Gastroenterological disorders and diseases of Prostate, Bladder, Urethra, Uterine cavity, Stomach, GI, Urinary tract and Reproductive organs using Biomaterials, Laser & RF devices, Tissue ablative and Augmenting agents, Microsurgical instruments and Endoscopic accessories.
NeoScope™- - Endoscopic Diagnostic & Treatment System (Modification)	<b>Prosurg, Inc</b>	K120766	<p>The Prosurg's NeoScope (Cystourethroscope/ Cystoureteroscope / Cystonephroscope System (which includes the Digital video Endoscope and Video Capture Module) is intended for use to examine body cavities, hollow organs and canals in the body, in the Urinary tract, and can be percutaneously to examine the interior of the kidney and using additional accessories can be used to perform various diagnostic and therapeutic procedures.</p> <p>The Prosurg's Neoscope ( Hysteroscope) System (which includes the Digital Endoscope and Video Capture Module ) is intended for use to examine body cavities, hollow organs and canals in the body, in the Gynecological tract, and can be percutaneously to examine the interior of the uterus and using additional accessories can be used to perform various diagnostic and therapeutic procedures.</p>

**Safety and Effectiveness of the Device  
(Ref: 807.7H, 907.92, and 807.93)**

**NeoScope™- Digital Video Endoscopic System**

We have conducted safety and effectiveness testing of *NeoScope*™- Video Endoscope System and NeoScope Digital Endoscope ( Rigid & Flexible).

The NeoScope™- Video Endoscopic System includes Digital Video Endoscope (Rigid / Flexible) with built-in LED light source and video module connected to a video display monitoring devices or Laptop / Tablet computer. The Digital Video endoscope incorporates a miniature CMOS (Complimentary Medical Oxide Semi- conductor) imaging sensor and LEDs ( Light Emitting Diodes) located at the distal tip, connecting wires along the length of the rigid or flexible tubular structure and endoscope handle with USB interface. The Neoscope can be connected to a commercially available video monitor or laptop / tablet computer / mobile phone, using USB connecting cable. The proposed NeoScope Video System using digital video endoscope can provide maximum utility to physician for endoscopic diagnostic and therapeutic applications of the internal body organs. Test data based on laboratory testing have demonstrated that the product meets the specifications, is safe and effective for its intended use.

NeoScope™- Digital Video System and NeoScope Video Endoscope ( Rigid & Flexible) are safe and effective during endoscopic viewing of various body organs and disorders, for diagnostic and treatment procedures.

**Product Shelf Life:**

The recommended Shelf life of the NeoScope™- Digital Video Endoscopic System and NeoScope Digital Endoscope ( Rigid & Flexible) is one year. The product shelf life was determined as per Accelerated aging techniques, based on the assumptions that the chemical reactions involved in the deterioration of materials follow the Arrhenius reaction rate function. The sterilized products were subjected to environmental conditions & were tested to confirm product performance and packaging integrity specifications. The Shelf life report is attached herewith for your review and approval. The Real –Time aging test for 12 month will be initiated out upon completion of first manufacturing production lot.

**(14) Form FDA 3654 :**

The Form 3654 for relevant standards used in 510K application is submitted herewith for your review and approval. ( Please see attached)



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 10 2004

Mr. Terrence E. Sullivan  
Director, Regulatory Affairs  
ACMI Corporation  
136 Turnpike Road  
SOUTHBOROUGH MA 01772-2104

Re: K042225  
Trade/Device Name: ACMI® INVISIO ICN  
Regulation Number: 21 CFR §876.1500  
Regulation Name: Endoscope and accessories  
Product Codes: 78 FAJ and FGA  
Regulation Number: 21 CFR §878.4160  
Regulation Name: Surgical camera and accessories  
Product Code: 79 FWF  
Regulatory Class: II  
Dated: August 16, 2004  
Received: August 17, 2004

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2

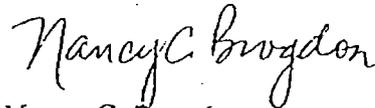
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

ACMI® INVISIO ICN  
ACMI Corporation  
136 Turnpike Road  
Southborough, MA 01772

Special 510(k) Notification  
Statement of Intended Use  
August 16, 2004

Device Name: ACMI® INVISIO ICN

K042225

510(k) Number:

Indications for use:

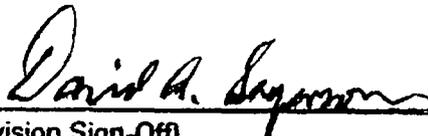
The ACMI® INVISIO ICN (ICN) Digital Flexible CystoNephroscope System (which includes the ICN scope and Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:  X  OR Over-the-Counter Use:

(Per 21 CFR 801.109)



(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

K042225

SEP 10 2004

**510(k) Summary of Safety and Effectiveness**

*K042225*

**ACMI Corporation  
ACMI® INVISIO ICN**

*Pg 1 of 2*

**General Information**

Manufacturer: ACMI Corporation  
136 Turnpike Rd.  
Southborough, MA 01772-2104

Establishment Registration Number: 2020483

Contact Person: Terrence E. Sullivan  
Director, Regulatory Affairs

Date Prepared: August 16, 2004

**Device Description**

Classification Name: Endoscope and accessories  
(21 CFR 876.1500), Class II  
Surgical camera and accessories  
(21 CFR 878.4160), Class I

Trade Name: ACMI® INVISIO ICN

Generic/Common Name: Endoscope, Video Camera and accessories

**Predicate Device**

ACMI® ECN Video CystoNephroscope System                      K030960

**Intended Uses**

The ACMI® INVISIO ICN (ICN) Digital Flexible CystoNephroscope System (which includes the ICN scope and Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures.

ACMI® INVISIO ICN  
ACMI Corporation  
136 Turnpike Road  
Southborough, MA 01772

Special 510(k) Notification  
Summary of Safety and  
Effectiveness  
August 16, 2004

Page 2 of 2

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### **Product Description**

Like the predicate ACMI® Electronic Video CystoNephroscope (ECN) System, the ACMI® INVISIO ICN (ICN) is a flexible endoscope that incorporates CMOS (complimentary medical oxide semi-conductor) sensor technology to generate an image. The ICN can be introduced either through the urethra into the bladder or through a percutaneous tract into the abdominal cavity or kidney.

The ICN incorporates the same basic video imaging technology located in the endoscope as the predicate device. There is a miniature CMOS sensor located in the distal tip, wiring running through the endoscope shaft, a printed circuit board (PCB), a light-emitting diode (LED) light source located in the handle, and an electrical cord that connects the endoscope to the Camera Control Unit.

Like the predicate device, the ICN uses the same Camera Control Unit (CCU) that contains printed circuits boards (PCBs), software, power supply and power cables to process and display the images transmitted by the camera.

This Special 510(k) proposes modifications in the proximal handle design, a reduction in flexible shaft outer diameter, elimination of the secondary active deflection mechanism, and a minor software algorithm modification for the ACMI® INVISIO ICN. The indications for use, principles of operation, working channel length and diameter of the ACMI® INVISIO ICN remain the same as in the predicate device.

### **Summary of Safety and Effectiveness**

The proposed modifications for the ACMI® INVISIO ICN, as described in this submission, are substantially equivalent to the predicate device. The proposed modification in design specifications, performance specifications, dimensional specifications, and software specifications are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.



This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Device Name:** ACMI® DUR-Digital Ureteroscope and Choledochoscope System

**510(k) Number:** *K 060269*

**Indications for use:**

The ACMI® DUR-Digital Ureteroscope and Choledochoscope (DUR®-D) System (which includes the DUR-Digital Invisio™ Flexible Ureteroscope and Choledochoscope and IDC Invisio™ Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures.

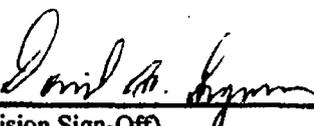
The DUR®-D System is also indicated for the examination of bile ducts, and using additional accessories, to perform various diagnostic and therapeutic procedures during cholecystectomy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:  **X**  **OR** Over-the-Counter Use:

(Per 21 CFR 801.109)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number *K060269*

MAR 31 2006

Traditional 510(k) Notification  
510(k) Summary  
January 30, 2006

510(k) Summary of Safety and Effectiveness  
ACMI Corporation  
ACMI® DUR-Digital Ureteroscope and Choledochoscope System

K060269  
Pg. 1 of 2

**General Information**

Manufacturer: ACMI Corporation  
136 Turnpike Rd.  
Southborough, MA 01772-2104

Contact Person: Terrence E. Sullivan  
Director, Regulatory Affairs  
Tel. #: 508-804-2739  
Fax #: 508-804-2624

Date Prepared: January 30, 2006

**Device Description**

Classification Name: Endoscope and accessories  
(21 CFR 876.1500), Class II  
Surgical camera and accessories  
(21 CFR 878.4160), Class I

Trade Name: ACMI® DUR-Digital Ureteroscope and  
Choledochoscope System (DUR®-D)

Generic/Common Name: Endoscope, Video Camera and accessories

**Predicate Devices**

ACMI® Invisio™ ICN K042225  
ACMI DUR®-8E K012925 and K023358

**Intended Uses**

The ACMI® DUR-Digital Ureteroscope and Choledochoscope (DUR®-D) System (which includes the DUR-Digital Invisio™ Flexible Ureteroscope and Choledochoscope and IDC Invisio™ Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures.

The DUR®-D System is also indicated for the examination of bile ducts, and using additional accessories, to perform various diagnostic and therapeutic procedures during cholecystectomy.

### **Product Description**

The ACMI® DUR®- Digital Ureteroscope and Choledochoscope (DUR®-D) is a flexible endoscope that incorporates CMOS (complimentary medical oxide semiconductor) sensor technology to generate an image. There is a miniature CMOS sensor located in the distal tip, wiring running through the endoscope shaft, a printed circuit board (PCB), a light-emitting diode (LED) light source located in the handle, and an electrical cord that connects the endoscope to the Camera Control Unit.

The DUR®-Digital Ureteroscope and Choledochoscope can be introduced either through the urethra into the bladder or through a percutaneous tract into the abdominal cavity or kidney. The DUR®- Digital Ureteroscope and Choledochoscope may also be used to manage biliary calculi in a choledochoscope indication. The DUR®-D System uses a Camera Control Unit (CCU) that contains printed circuits boards (PCBs), software, power supply and power cables to process and display the images transmitted by the camera.

### **Technological Characteristics and Substantial Equivalence**

The ACMI® DUR-Digital Ureteroscope and Choledochoscope (DUR®-D) System, utilizes features incorporated into the following legally marketed predicate devices:

The ACMI® DUR-Digital Ureteroscope and Choledochoscope (DUR®-D) System utilizes the same flexible endoscope technology design as those used in the predicate DUR®-8E device (K012925 and K023358).

The DUR®- Digital Ureteroscope and Choledochoscope is dimensionally similar to the predicate DUR®-8E, having the same working channel diameter and length, and utilizes the same materials in its construction as the predicate DUR®-8E.

The DUR®-Digital Ureteroscope and Choledochoscope incorporates the same basic video imaging technology located in the endoscope as the predicate ACMI® Invisio™ ICN System (K042225).

Like the predicate DUR®-8E, the ACMI® DUR®-Digital Ureteroscope and Choledochoscope (DUR®-D) System is indicated for use in therapeutic and diagnostic procedures in the entire intrarenal collecting system, and may also be used to manage biliary calculi.

*K060269 pg 3 of 3*

During design verification, the performance of the DUR®-D was compared against the physical performance characteristics of the predicate DUR®-8E and the digital visualization characteristics of the predicate Invisio™ ICN. Testing demonstrated that the performance requirements were met, and that the DUR®-D exhibited comparable performance characteristics to both the predicate DUR®-8E and predicate Invisio™ ICN.

In summary, the ACMI® DUR-Digital Ureteroscope and Choledochoscope (DUR®-D) System is substantially equivalent to the predicate devices and presents no new questions of safety or efficacy.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 20 2009

Mr. Graham A. L. Baillie, MS  
Senior Regulatory Affairs Specialist  
Gyrus ACMI, Inc.  
136 Turnpike Road  
Southborough MA 01772

Re: K090814  
Trade/Device Name: Gyrus ACMI® Invisio® ICN  
Regulation Number: 21 CFR 876.5130  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: FAJ  
Dated: March 23, 2009  
Received: March 25, 2009

Dear Mr. Baillie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2

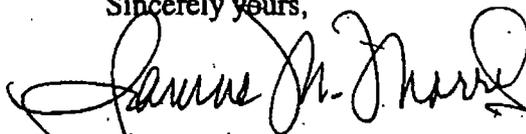
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number: K090814

Device Name: Gyrus ACMI® Invisio® ICN

**Indications for Use:**

The Gyrus ACMI® Invisio® ICN (CystoNephroscope) System (which includes the ICN Endoscope and Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures.

Prescription Use:  X   
(Per 21 CFR 801.109)

AND/OR

Over-the-Counter Use: \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K090814

Gyrus ACMI® Invisio® ICN

Gyrus ACMI, Inc.  
136 Turnpike Road  
Southborough, MA 01772

Special 510(k) Notification  
Summary of S & E  
Mar 23, 2009

K090814

**510(k) Summary of Safety and Effectiveness**  
**Gyrus ACMI, Inc.**  
**Gyrus ACMI® Invisio® ICN**

pg 1 of 2

**General Information**

APR 20 2009

Manufacturer: Gyrus ACMI, Inc.  
136 Turnpike Rd.  
Southborough, MA 01772-2104

Establishment Registration Number: 3003790304

Contact Person: Graham A. L. Baillie, MS  
Senior Regulatory Affairs Specialist

Date Prepared: Mar , 2009

**Device Description**

Classification Name: Endoscope and accessories  
(21 CFR 876.1500), Class II  
Gastroenterology & Urology Panel  
Surgical camera and accessories  
General & Plastic surgery Panel  
(21 CFR 878.4160), Class I

Trade Name: Gyrus ACMI® Invisio® ICN

Generic/Common Name: Endoscope, Video Camera and accessories

**Predicate Device**

ACMI® Invisio® ICN  
CystoNephroscope System K042225

**Intended Uses**

The Gyrus ACMI® Invisio® ICN Digital Flexible CystoNephroscope System (which includes the ICN scope and Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures.

ACMI® Invisio® ICN  
Gyrus ACMI, Inc.  
136 Turnpike Rd.  
Southborough, MA 01772

Special 510(k) Notification  
Summary of S & E  
Statement  
Mar 23, 2009

**Product Description**

K090814  
Pg 2 of 2

Like the predicate ACMI® Invisio® ICN CystoNephroscope System, the Gyrus ACMI® Invisio® ICN is a flexible endoscope that incorporates CMOS (complimentary medical oxide semi-conductor) sensor technology to generate an image. The ICN can be introduced either through the urethra into the bladder or through a percutaneous tract into the abdominal cavity or kidney.

The ICN incorporates the same basic video imaging technology located in the endoscope as the predicate device. There is a miniature CMOS sensor located in the distal tip, wiring running through the endoscope shaft, a printed circuit board (PCB), a light-emitting diode (LED), light source located in the handle, and an electrical cord that connects the endoscope to the Camera Control Unit.

Like the predicate device, the ICN uses the same Camera Control Unit (CCU) that contains printed circuits boards (PCBs), software, power supply and power cables to process and display the images transmitted by the camera.

This Special 510(k) proposes video sensor performance modifications to the ACMI® Invisio® ICN. The indications for use, labeling, principles of operation, materials and overall dimensions of the proposed Gyrus ACMI® Invisio® ICN remain the same as in the predicate device.

**Summary of Safety and Effectiveness**

The proposed modifications for the Gyrus ACMI® Invisio® ICN, as described in this submission, are substantially equivalent to the predicate device. The proposed modification in design specifications, performance specifications, and software specifications are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 10 2004

Mr. Terrence E. Sullivan  
Director, Regulatory Affairs  
ACMI Corporation  
136 Turnpike Road  
SOUTHBOROUGH MA 01772-2104

Re: K042225  
Trade/Device Name: ACMI<sup>®</sup> INVISIO ICN  
Regulation Number: 21 CFR §876.1500  
Regulation Name: Endoscope and accessories  
Product Codes: 78 FAJ and FGA  
Regulation Number: 21 CFR §878.4160  
Regulation Name: Surgical camera and accessories  
Product Code: 79 FWF  
Regulatory Class: II  
Dated: August 16, 2004  
Received: August 17, 2004

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

ACMI® INVISIO ICN  
ACMI Corporation  
136 Turnpike Road  
Southborough, MA 01772

K042225  
Pg 2 of 2

Special 510(k) Notification  
Summary of Safety and  
Effectiveness  
August 16, 2004

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### **Product Description**

Like the predicate ACMI® Electronic Video CystoNephroscope (ECN) System, the ACMI® INVISIO ICN (ICN) is a flexible endoscope that incorporates CMOS (complimentary medical oxide semi-conductor) sensor technology to generate an image. The ICN can be introduced either through the urethra into the bladder or through a percutaneous tract into the abdominal cavity or kidney.

The ICN incorporates the same basic video imaging technology located in the endoscope as the predicate device. There is a miniature CMOS sensor located in the distal tip, wiring running through the endoscope shaft, a printed circuit board (PCB), a light-emitting diode (LED) light source located in the handle, and an electrical cord that connects the endoscope to the Camera Control Unit.

Like the predicate device, the ICN uses the same Camera Control Unit (CCU) that contains printed circuits boards (PCBs), software, power supply and power cables to process and display the images transmitted by the camera.

This Special 510(k) proposes modifications in the proximal handle design, a reduction in flexible shaft outer diameter, elimination of the secondary active deflection mechanism, and a minor software algorithm modification for the ACMI® INVISIO ICN. The indications for use, principles of operation, working channel length and diameter of the ACMI® INVISIO ICN remain the same as in the predicate device.

### **Summary of Safety and Effectiveness**

The proposed modifications for the ACMI® INVISIO ICN, as described in this submission, are substantially equivalent to the predicate device. The proposed modification in design specifications, performance specifications, dimensional specifications, and software specifications are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.

ACMI® INVISIO ICN  
ACMI Corporation  
136 Turnpike Road  
Southborough, MA 01772

SEP 10 2004

Special 510(k) Notification  
Statement of Intended Use  
August 16, 2004

510(k) Summary of Safety and Effectiveness  
ACMI Corporation  
ACMI® INVISIO ICN

K04 2225  
Pg 1 of 2

**General Information**

Manufacturer: ACMI Corporation  
136 Turnpike Rd.  
Southborough, MA 01772-2104

Establishment Registration Number: 2020483

Contact Person: Terrence E. Sullivan  
Director, Regulatory Affairs

Date Prepared: August 16, 2004

**Device Description**

Classification Name: Endoscope and accessories  
(21 CFR 876.1500), Class II  
Surgical camera and accessories  
(21 CFR 878.4160), Class I

Trade Name: ACMI® INVISIO ICN

Generic/Common Name: Endoscope, Video Camera and accessories

**Predicate Device**

ACMI® ECN Video CystoNephroscope System K030960

**Intended Uses**

The ACMI® INVISIO ICN (ICN) Digital Flexible CystoNephroscope System (which includes the ICN scope and Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures.

ACMI® INVISIO ICN  
ACMI Corporation  
136 Turnpike Road  
Southborough, MA 01772

Special 510(k) Notification  
Statement of Intended Use  
August 16, 2004

Device Name: ACMI® INVISIO ICN

*K042225*

510(k) Number:

Indications for use:

The ACMI® INVISIO ICN (ICN) Digital Flexible CystoNephroscope System (which includes the ICN scope and Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:  X  OR Over-the-Counter Use:

(Per 21 CFR 801.109)

*David A. Seymour*

(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number           *K042225*

Page 2

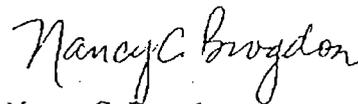
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 30 2004

Olympus Winter & Ibe, GmbH  
c/o Ms. Tina Steffanie-Oak  
Associate Manager, Regulatory Affairs  
Olympus America, Inc.  
Two Corporate Center Drive  
MELVILLE NY 11747

Re: K033651

Trade/Device Name: OLYMPUS VIDEO URETEROSCOPE, NTSC (S-1546/2)  
Modification to A2560 Ureteroscope (K951855)

Regulation Number: 21 CFR §876.1500

Regulation Name: Endoscope and accessories

Regulatory Class: II

Product Code: 78 FGB

Dated: January 21, 2004

Received: January 22, 2004

Dear Ms. Steffanie-Oak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2

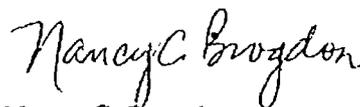
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

JAN 9 8 2014

K033651

**SMDA 5120(k) SUMMERY**

**OLYMPUS VIDEO URETEROSCOPE, NTSC**

**A. Submitter's Name, Address and Phone and Fax Numbers**

Name & Address of manufacturer: Olympus Winter & Ibe, GmbH  
Kuehnstr. 61  
Hamburg 22045, Germany  
Phone: +49 40 669 66-0  
Fax: +49 40 668 15 91  
Registration Number: 8010313

**B. Name of Contact Person**

Address of initial importer and contact: Olympus America  
2 Corporate Center Drive  
Melville, N.Y. 11747  
Registration Number: 2429304  
Contact: Tina Steffanie-Oak, Associate R.A. Manager  
Phone: 631-844-5477  
Fax: 631-844-5554

**C. Device name, Common Name, Classification Name and Predicate Devices**

Trade NAME: OLYMPUS VIDEO URETEROSCOPE, NTSC  
Common Name: Ureterscope and Accessories  
Classification: 21 CFR 876.1500 Endoscope and accessories.  
Class II FDA Product Code FGB  
Predicate Device: A2560 510(k)# K951855

**D. Description of the Device**

The subject device is used for endoscopic diagnosis and treatment within the urethra, bladder, and ureter. The optical system is modified from image guide to CCD and the resolution is improved.

**E. Intended Use of the Device**

This instrument has been designed to be used with an Olympus video system, light source, documentation equipment, display monitor, endo-therapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the urethra, bladder, and ureter.

K033651

510(k) Number (if known): ~~Not assigned yet~~ K033651

Device Name: Olympus video ureteroscope, NTSC

**Indications for Use:** This instrument has been designed to be used with an Olympus video system, light source, documentation equipment, display monitor, endo-therapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the urethra, bladder, and ureter.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

David R. Lynn  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K033651



OCT 5 - 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Robert L. Casarsa  
Quality Assurance Manager  
Richard Wolf Medical Instruments Corporations  
353 Corporate Woods Parkway  
VERNON HILLS IL 60061-3110

Re: K051176  
Trade/Device Name: Flexible Video Cystoscope / Choledochoscope  
(Models 7308.061 and 7308.066)  
Regulation Number: 21 CFR §876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Codes: FBN and FAJ  
Dated: September 7, 2005  
Received: September 9, 2005

Dear Mr. Casarsa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## 5.0 Indications for Use

510(k) Number: K05 1176

Device Name: Flexible Video Cystoscope / Choledochoscope

**Indications For Use:** The Flexible Video Cystoscope is used for visualizing body cavities and organs via natural passages. For examination, diagnosis and/or therapy in conjunction with endoscopic accessories/ auxiliary instruments through the scope's working channel. The scope is used in the medical disciplines of

- Urology (urogenital tract, cystoscopy, nephroscopy)
- Surgery (choledochoscopy)

Prescription Use

(Part 21 CFR 801 Subpart D)

~~AND/OR~~

Over-The Counter

(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

David A. Leggett

(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K051176

*K051176  
pg 1 of 2*



**OCT 5 - 2005**

353 Corporate Woods Parkway  
Vernon Hills, IL 60061-3110  
Phone: 847-913-1113  
Customer Service: 800-323-WOLF (9653)  
www.richardwolfusa.com

**12.0 510(k) Summary of Safety and Effectiveness**

<b>Submitter:</b>		Date of Preparation: <b>May 4, 2005</b>	
Company / Institution name: <b>RICHARD WOLF MEDICAL INSTRUMENTS CORP.</b>		FDA establishment registration number: <b>14 184 79</b>	
Division name (if applicable): <b>N.A.</b>		Phone number (include area code): <b>( 847 ) 913 1113</b>	
Street address: <b>353 Corporate Woods Parkway</b>		FAX number (include area code): <b>( 847 ) 913 0924</b>	
City: <b>Vernon Hills</b>	State/Province: <b>Illinois</b>	Country: <b>USA</b>	ZIP / Postal Code: <b>IL 60061</b>
Contact name: <b>Mr. Robert L. Casarsa</b>			
Contact title: <b>Quality Assurance Manager</b>			
<b>Product Information:</b>			
Trade name: <b>Flexible Video-Endoscope</b>		Model number: <b>7308.061, 7308.066</b>	
Common name: <b>Flexible Video Cystoscope / Choledochoscope</b>		Classification name: <b>Cystoscope / Nephroscope /Choledochoscope</b>	
<b>Information on devices to which substantial equivalence is claimed:</b>			
510(k) Number	Trade or proprietary or model name	Manufacturer	
1 K980401	1 Flexible Fiberscopes and Accessories	1 Richard Wolf	
2 K 021074	2 Cysto-Videoscope VISERA CYF-V, CYF-VA	2 Olympus	
3 K30960	3 Digital Flexible Cysto-Videoscope DCN	3 ACMI	
4 K023659	4 1 CCD Endocam 5520 System	4 Richard Wolf	
5 K983279	5 1 CCD Multi Endocam 5502 with Electronic CCD Endoscope 4934.551	5 Richard Wolf	

R 651176-0287



**1.0 Description**

The submitted flexible video cystoscopes / choledochoscopes are a modification of the Richard Wolf flexible fiber-cystoscopes. The submitted flexible video cystoscopes have a CCD video image sensor for generating a video image with a camera controller instead of an image fiber light guide. The submitted video cystoscopes connect to the Richard Wolf camera system 5520.

**2.0 Intended Use**

The Flexible Video Cystoscope is used for visualizing body cavities and organs via natural and surgically generated passages. For examination, diagnosis and/or therapy in conjunction with endoscopic accessories/auxiliary instruments through the scope's working channel. The scope is used in the medical disciplines of Urology ( urogenital tract, cystoscopy, nephroscopy) and Surgery (choledochoscopy).

**3.0 Technological Characteristics**

The videoscopes have similar dimensions, working channels and design as the Richard Wolf flexible fiber-cystoscopes. Both cystoscopes are designed with a control lever for locking the tip in any angled position. Two different control directions are available, i.e. the endoscope is deflected either upward or downward upon activating the control lever proximally or distally. The tips are angled approximately 45° and angled. This makes the insertion into the urethra easier and more comfortable for male patients. The adapter with instrument port, irrigation and drain stopcocks and optional biopsy valve is removable. The new style ergonomic handle is equipped with two remote control buttons that control the camera function.

**4.0 Substantial Equivalence**

The submitted devices pose the same type of questions about safety or effectiveness as existing devices and the new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing 510(k) devices sold by Richard Wolf, Olympus and ACMI.

**5.0 Performance Data**

The flexible videoscopes 7301.061 / 7301.066 are designed to meet the standards IEC601-1/ UL2601-1 and IEC601-1-2.

**6.0 Clinical Tests**

No special clinical tests performed.

**7.0 Conclusions Drawn**

These devices are designed and tested to guarantee the safety and effectiveness, when used according to the instructions manual.

By: Robert L. Casarsa  
Robert L. Casarsa  
Quality Assurance Manager

Date: May 4, 2005

\* \* \* COMMUNICATION RESULT REPORT ( JUN. 26. 2012 1:09PM ) \* \* \*

FAX HEADER 1:  
FAX HEADER 2:

TRANSMITTED/STORED : JUN. 26. 2012 1:04PM  
MODE OPTION

ADDRESS

RESULT

PAGE

6947 MEMORY TX

4089451390

OK

9/9

REASON FOR ERROR  
E-1) HANG UP OR LINE FAIL  
E-3) NO ANSWER

E-2) BUSY  
E-4) NO FACSIMILE CONNECTION



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Mr. Ashvin Desai  
Manager, Regulatory Affairs  
ProSurg, Inc.  
2193 Trade Zone Boulevard  
SAN JOSE CA 95131

JUN 25 2012

Re: K120766  
Trade Name: Endoscopic Diagnostic & Treatment System (Modification)  
Dated: March 5, 2012  
Received: May 8, 2012.

Dear Mr. Desai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following.

Device Description

1. Please provide a more detailed description of the device and its various configurations, including:
  - a. identification and description of each component/accessory, including complete details regarding the thermal energy for tissue ablation and removal using RF (Monopolar I Bipolar), Laser, Microwave energy, Cryo energy and Microsurgical instrumentation), and
  - b. a complete list of all compatible endoscope designs (currently listed as "Storz, Wolf, Circon/Gyrus/ACMI, Olympus & others," which is open-ended).

Predicate Comparison

2. You have provided a limited comparison between your devices and the predicate device to determine substantial equivalence. To support the substantial equivalence of your proposed devices and the predicate devices you identify in your 510(k), please provide a detailed tabular comparison of the specifications of your devices and the predicates. For devices with the same intended use as the predicate devices, we would expect to see:



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Mr. Ashvin Desai  
Manager, Regulatory Affairs  
ProSurg, Inc.  
2193 Trade Zone Boulevard  
SAN JOSE CA 95131

JUN 25 2012

Re: K120766  
Trade Name: Endoscopic Diagnostic & Treatment System (Modification)  
Dated: March 5, 2012  
Received: May 8, 2012

Dear Mr. Desai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following.

Device Description

1. Please provide a more detailed description of the device and its various configurations, including:
  - a. identification and description of each component/accessory, including complete details regarding the thermal energy for tissue ablation and removal using RF (Monopolar I Bipolar), Laser, Microwave energy, Cryo energy and Microsurgical instrumentation), and
  - b. a complete list of all compatible endoscope designs (currently listed as "Storz, Wolf, Circon/Gyrus/ACMI, Olympus & others," which is open-ended).

Predicate Comparison

2. You have provided a limited comparison between your devices and the predicate device to determine substantial equivalence. To support the substantial equivalence of your proposed devices and the predicate devices you identify in your 510(k), please provide a detailed tabular comparison of the specifications of your devices and the predicates. For devices with the same intended use as the predicate devices, we would expect to see:

- a. the comparisons in terms of indications for use, technology, physical dimensions, materials, design and performance specifications including any testing,
- b. a discussion as to whether those characteristics are the same as the predicates of if they are different, and
- c. why those differences do not raise new questions of safety and effectiveness and demonstrates that the proposed devices are at least as safe and effective as the legally marketed devices.

### Labeling

3. You should include instructions for use in addition to the labeling provided which addresses:
  - a. The intended use statement should include specific indications for use, clinical setting, a defined target population, etc. In your case you would have to provide separate labeling for each type of endoscope including the accessories you plan to provide.
  - b. Directions for use should include:
    - i) instructions on how to prepare each type of endoscope for patient use;
    - ii) how to insert and remove each type of endoscope;
    - iii) other specific physician labeling as to the principles of operation for each type of endoscope and accessories you plan to provide;
    - iv) a statement of whether each type of endoscope is intended as single use/disposable or reusable. If endoscope is to be labeled as reusable for the same patient, provide adequate instructions about how to clean and sterilize the endoscope, as well as validation as to anticipated changes in device function secondary to reprocessing (e.g., change in antimicrobial status). Functional test procedures for the endoscope prior to use should also be provided, e.g., optical functioning. A separate reprocessing manual may be required.
    - v) a separate user's manual may be required for the principles of operation of each type of endoscope including the accessories.
  - c. Contraindications, precautions, warnings, and adverse effects should be included within the labeling for each type of endoscope including the accessories you plan to provide.

See also Labeling Requirements, at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm>.

#### Shelf Life

4. You have stated that your shelf life determination is for one year for your device however, you have not included the reports to support your one year shelf life. Your shelf life should be supported by appropriate bench tests and/or sterilization and packaging validation. Please refer to the “Updated 501(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA available at the following web site: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm>.

#### Biocompatibility

5. You have stated that materials used to manufacture the subject device are identical to the predicate device and are safe and biocompatible materials that are widely used in the medical industry. Based on your statement, we cannot determine whether you have conducted biocompatibility testing of your final devices according to ISO 10993 standards. We would expect to see biocompatibility testing for limited contact of less than 24 hours to include but not limited to mucosal irritation or intracutaneous reactivity, cytotoxicity, and sensitization on your final sterilized devices. Please note that the manufacturing process, including the sterilization process, can significantly affect the biocompatibility of the final device due to the use of different additives and the formation of various byproducts in manufacturing process. Please clarify whether you have conducted biocompatibility testing of your final, finished, sterilized device as recommended by FDA blue book memo G95-1 and the ISO 10993-1:2009 standard. Please provide testing reports and standards forms for each testing if the test was conducted according to FDA recognized standards. Alternatively, please provide appropriate justification that your device is comprised of the exact same materials and exposed to the same manufacturing processes as the predicate device. Please refer to the guidance documents titled *Blue Book Memo, G95-1, Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices* which can be found at the following web site <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm>.

#### Software

6. You need to address the software evaluation and performance requirements, please provide the following:

- a. Level of Concern

You should provide the level of concern, justification and supporting rationale.

b. Software Description

You should include a summary overview of the features and software operating environment including information on programming language, hardware platform, operating system and off-the-shell software.

c. Software Hazard Analysis

You should include a tabular description of identified hardware and software hazards, including severity assessment and mitigation(s), clinical hazards, method of control of the hazards and results of evaluating the correct implementation.

d. Software Requirements Specifications (SRS)

You should include a detailed listing of all of the specific requirements of the software including specifications of the functional requirements for the software in the digital video processor.

e. Architecture Design Charts

You should include detailed depiction of functional units and software modules; it may also include state diagrams as well as flow charts.

f. Software Design Specifications (SDS)

You should include a detailed SDS document, which describes how the SRS are implemented.

g. Traceability Analysis

You should include traceability matrix among requirements, specifications, identified hazards and mitigation(s), including traceability information on risk mitigation measures and implementation of software design specifications, and verification and validation testing.

h. Development Plan

You should include a summary of the software life cycle development plan, including the configuration management and maintenance plan documents. For a major level of concern, this documentation should also include an annotated list of control documents generated during the development process.

i. Verification, Validation, and Testing

For a minor level of concern, this documentation should include the software functional test plan, pass/fail criteria, and results. For a moderate level of concern, this documentation should include a description of verification and validation (V&V) activities at the unit, integration, and system level, as well as system level test protocol, including pass/fail criteria, and tests results. For a major level of concern, this information should include a description of V&V activities at the unit, integration, and system level as well as unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.

j. Revision Level History

You should include a revision history log, including release version number and date to document the history of software revisions generated during the development of the software.

k. Unresolved Anomalies (Bugs)

For moderate and major, the documentation should include a list of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.

l. Off-the-Shelf (OTS) Software

You should provide information on any OTS software.

m. Cyber and Information Security

You should address security issues associated with network communications since the device may transmit endoscopic images to external servers (such as DICOM servers) via network communications. The firm should also provide information, as appropriate, on the Cybersecurity aspects of their device, including but not limited to, the following facets of information security with respect to communications: confidentiality, integrity, availability and accountability.

Electromagnetic Compatibility

7. To evaluate the electromagnetic compatibility, safety, effectiveness, and reliability of your device according to EMC standard IEC 60601-1-2:2007–Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests – please provide the results of your testing and conclusions for those that are relevant to this standard. Additionally, please provide the following information in order to understand how the testing is performed:

- a. A summary of the testing that was done;
- b. The requirements of the standard that were met (including immunity test levels);
- c. The pass/fail criteria used;
- d. The functions of the device that were considered to be essential performance;
- e. The performance of the device during each immunity test (e.g., degradation observed);
- f. Identification and justification for any of the standard 's allowances that were used;
- g. A description of and justification for any deviations from the requirements of the standard;
- h. Evidence of compliance with the standard' s labeling (identification, marking and documents) requirements;
- i. If any device modifications were needed in order to pass any of the EMC testing, a description of these modifications and a statement that they will all be incorporated into the production units.

#### Electrical Safety

8. You did not provide the electrical safety testing of your device under normal conditions and under the operating conditions which include the use of specified electrical surgical units. To ensure that your device is electrically safe according to IEC 60601-1-1:2000 Medical Electrical Equipment – Part 1-1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems and IEC 60601-2-18:1996 + A1:2000 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Endoscopic Equipment – please perform the electrical safety testing of your active device with compatible electrosurgical units and connectors and revise your instructions for use to include compatible electrosurgical units. Please also provide the input parameters of your device that is required to achieve your specified output parameters.

#### Mechanical Safety

9. You did not provide a complete performance testing report summarizing the bench testing of your device and its outcomes, including the number of devices tested or if tests were performed on the final sterilized device. To determine the safety and effectiveness of your device please provide a complete report of your product performance testing, including but not limited to the following:

- a. Leak and pull testing;
- b. Handle strength testing.

Thermal Safety

10. You did not provide the thermal safety testing of your device. To ensure that your device is thermally safe according to IEC 60601-2-18:1996 + A1:2000 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Endoscopic Equipment – please provide the results of your testing and conclusions for the device that applies to this performance standard.

Performance Testing - Bench

(b)(4)



The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

**If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, “FDA and**

**Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment” at**

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf>. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter and would like to set up a teleconference, please contact Mary Beth O'Brien, RN, MSN at (301) 796-6557. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100, or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Glenn B. Bell, Ph.D.  
Acting Chief, Urology and Lithotripsy  
Devices Branch  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

Enclosure (K120766)

**Software Test Requirements:**

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices includes the following:

- IEC 62304:2006 Medical Device Software - Software Life Cycle Processes
- <http://www.fda.gov/cdrh/ode/software.html>
- “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf>, 5/11/05
- “Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices”  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073779.pdf>, 9/9/1999
- “General Principles of Software Validation; Final Guidance for Industry and FDA Staff”  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085371.pdf>, 1/11/2002
- “Guidance for Industry. Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software”  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf>, 1/14/05

**K120766 – ProSurg, Inc.**

cc: DMC - 2 copies  
ODE/DRGUD/ULDB (MOA)

**Drafted:** MOA:6.15.2012  
**Final:** MOA:clr:6.15.2012  
**Revised Final:** MOA:clr:6.25.12

Division/Branch	Last Name	Date	Division/Branch	Last Name	Date
DRGUD/ULDB	O'Brien	6/25/2012			
DRGUD/ULDB	Bill	25 June 2012			



Food and Drug Administration  
Office of Device Evaluation &  
Office of In Vitro Diagnostics

**COVER SHEET MEMORANDUM**

**From:** Reviewer Name Kathy E. Brewer Anderson  
**Subject:** 510(k) Number K120766  
**To:** The Record

Please list CTS decision code AI

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPreMarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE (select code below); Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NU NSE for new intended use AND new technology raising new questions of safety and effectiveness
- NP NSE for lack of performance data
- NS NSE no response
- NL NSE for lack of performance data AND no response
- NM NSE pre-amendment device call for PMAs (515i)
- NC NSE post-amendment device requires PMAs
- NH NSE for new molecular entity requires PMA
- TR NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	<i>Attach IFU</i>		
510(k) Summary /510(k) Statement	<i>Attach Summary</i>		
Truthful and Accurate Statement.	<i>Must be present for a Final Decision</i>		
Is the device Class III?			
If yes, does firm include Class III Summary?	<i>Must be present for a Final Decision</i>		
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )			
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies <b>only</b> : Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV or 301-796-8118

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age <= 21

Neonate/Newborn (Birth to 28 days)

Infant (29 days - < 2 years old)

Child (2 years - < 12 years old)

Adolescent (12 years - < 18 years old)

Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>)

Contact OC.

Regulation Number

Class\*

Product Code

(\*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review:

*Alan B. Bell*

(Branch Chief)

*UCDB*

(Branch Code)

*25 June 2012*

(Date)

Final Review:

(Division Director)

(Date)





DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional

K120766

Date: June 25, 2012
To: The Record
From: Mary E. O'Brien, RN, MSN

Office: CDRH/ODE
Division: DRGUD/ULDB

510(k) Holder: ProSurg, Inc.
Device Name: Endoscopic Diagnostic & Treatment System (modification)
Contact: A. Desai
Phone: 408-945-4044
Fax: 408-945-1300
Email: Ashvin@Prosurg.com

I. Purpose and Submission Summary

The 510(k), ProSurg, Inc., holder would like to introduce Endoscopic Diagnostic & Treatment System (modification) into interstate commerce.

Review Team:

Lead Reviewer: Mary Beth O'Brien, RN, MSN, ULDB
Engineer: Tuan Nguyen, Ph.D., Engineer, ULDB

II. Administrative Requirements

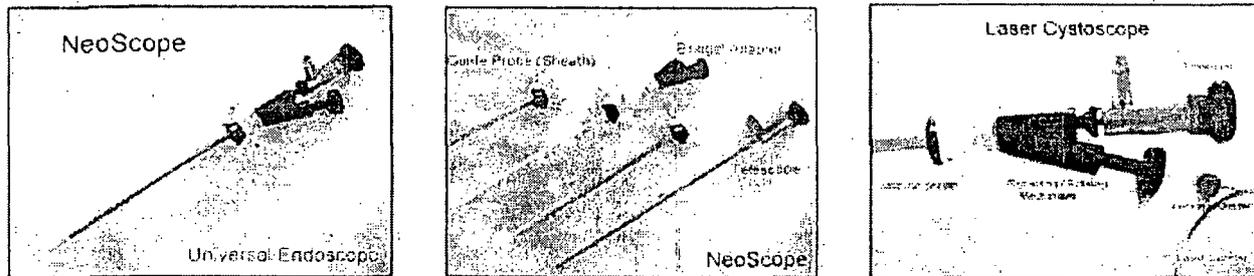
Table with 4 columns: Requirement, Page, Yes, No, N/A. Rows include Indications for Use page, Truthful and Accuracy Statement, 510(k) Summary or 510(k) Statement, and Standards Form.

III. Device Description

Table with 4 columns: Question, Yes, No, N/A. Rows include 'Is the device life-supporting or life sustaining?' and 'Is the device an implant (implanted longer than 30 days)?'

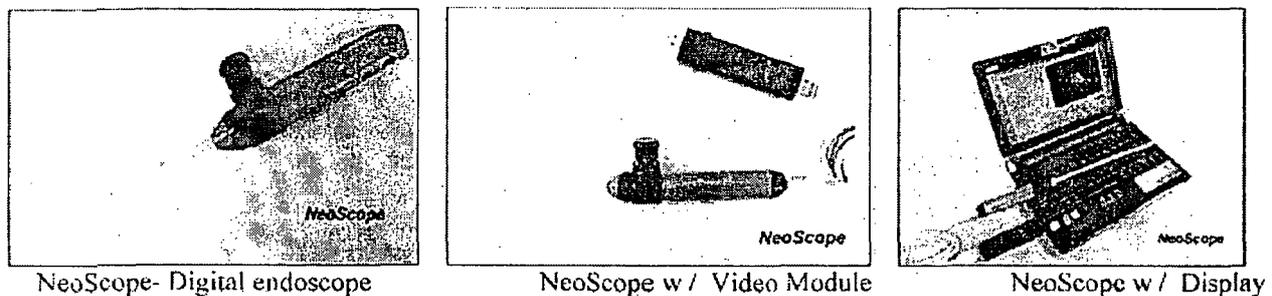
	Yes	No	N/A
Does the device design use software?		✓	
Is the device sterile?	✓		
Is the device reusable (not reprocessed single use)?		✓	
Are "cleaning" instructions included for the end user?		✓	

The NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) is a sterile, single-use modular device for endoscopic diagnostic and treatment. It is compatible with standard endoscopes and interchangeable accessories. The device consists of an outer guide probe, adapter, delivery system and a viewing scope. The outer guide probe is used for irrigation. The delivery system comprises the injection needle and probes for delivering treatment substance, tissue agents, imaging dyes and contrast agents, drugs, sclerosing agents and bio-toxins. It can also be used for delivering thermal energy for tissue ablation and removal using radio frequency (RF), laser, microwave energy, cryo energy. The device can be used in a variety of endoscopic functions such as cystoscope, resectoscope, nephroscope, hysteroscope, and laparoscope. The original NeoScope™ Endoscopic Diagnostic & Treatment System is shown in the following figure.



**Figure 1: The NeoScope™ Endoscopic Diagnostic & Treatment System**

The new NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) consists of a digital viewing endoscope with a LED light source and video module interface for display using commercially available monitoring devices. The new NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) with the proposed modification system is illustrated in the following figure.



**Figure 1: The NeoScope™ Endoscopic Diagnostic & Treatment System (Modification)**

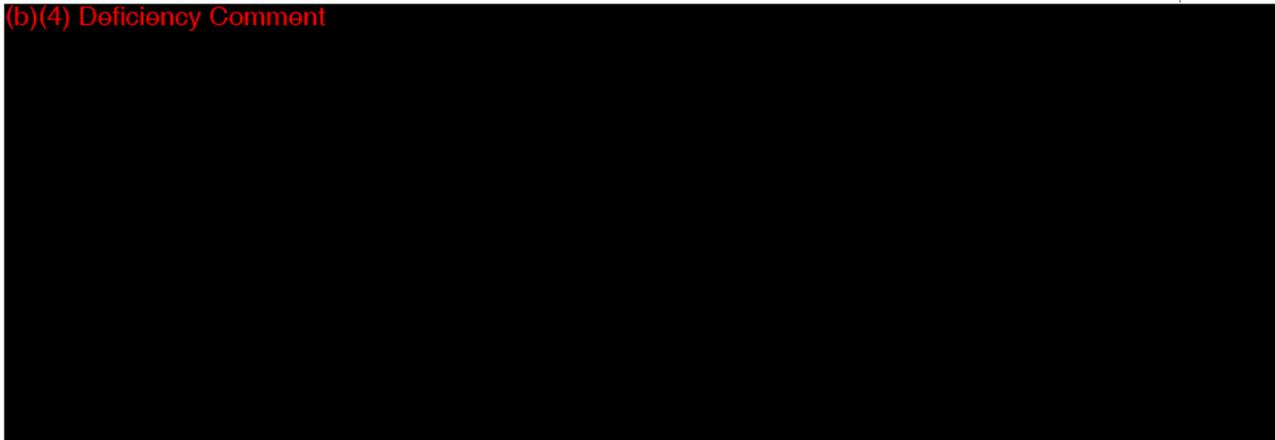
The subject device is designed for optimal visualization via digital imaging technology and to allow fluid irrigation and microsurgical instrument access. It can be introduced through various body cavities and opening.

The following table summarizes the product specifications of the NeoScope™ Endoscopic Diagnostic & Treatment System (Modification) along with their functions and descriptions.

**TABLE 2 – PRODUCT SPECIFICATIONS**

<b>Component/ Function</b>	<b>Description/Model</b>	<b>Material</b>
<b>Outer Guide Probe (Sheath)</b>	Diameter: 10 – 36 Fr Working Length: 10 – 45 cm	Probe: Stainless Steel 304/306 Handle: ABS Probe Tip: Silicon
<b>Delivery System</b>	Diameter: 3 – 10 Fr Working Length: 10 – 45 cm	Injection Needle: Stainless Steel 304/306 RF Electrodes: Stainless Steel 304/306 Catheters: Polyurethane RF Electrode Insulation: TPE/FEP Hub Connector: Polycarbonate Monopolar/Bipolar: Stainless Steel 304/306
<b>Conventional Viewing Endoscope</b>	Diameter: 1.0 – 12 mm Viewing Angle: 0°, 12°, 30°	Outer Tubing: Stainless Steel 304/306 Rod Lens Optics: Quartz
<b>Digital Endoscope (Rigid)</b>	Diameter: 5.0, 7.0, 10.0 mm Working Length: 15, 30, 40 cm Working Channel: 1, 1.5 mm	Rigid Outer Sheath: Stainless Steel 316 Optical Window: Quartz Handle: ABS
<b>Digital Endoscope (Flexible)</b>	Diameter: 5.0, 7.0, 10.0 mm Working Length: 30, 40, 70 cm Working Channel: 1, 1.5 mm	Flexible Outer Sheath: TFE Optical Window: Quartz Handle: ABS
<b>Accessories</b>	Video Interface Module Connecting Cable Video Display Monitor	Commercially Available
<b>Packaging</b>	Blister Tray Tyvek Lid Package	Commercially Available

(b)(4) Deficiency Comment



**IV. Indications for Use**

The NeoScope™ Endoscopic Diagnostic & Treatment System (modification) is intended for cystoscopic,

K120766  
ProSurg Endoscope

hysteroscopic, laparoscopic, resectoscopic and endoscopic treatment of urological, gynecological, gastroenterological disorders and diseases of prostate, bladder, urethra, uterine cavity, stomach, GI, urinary tract and reproductive organs using biomaterials, laser and RF devices, tissue ablative and augmenting agents, microsurgical instruments and endoscopic accessories

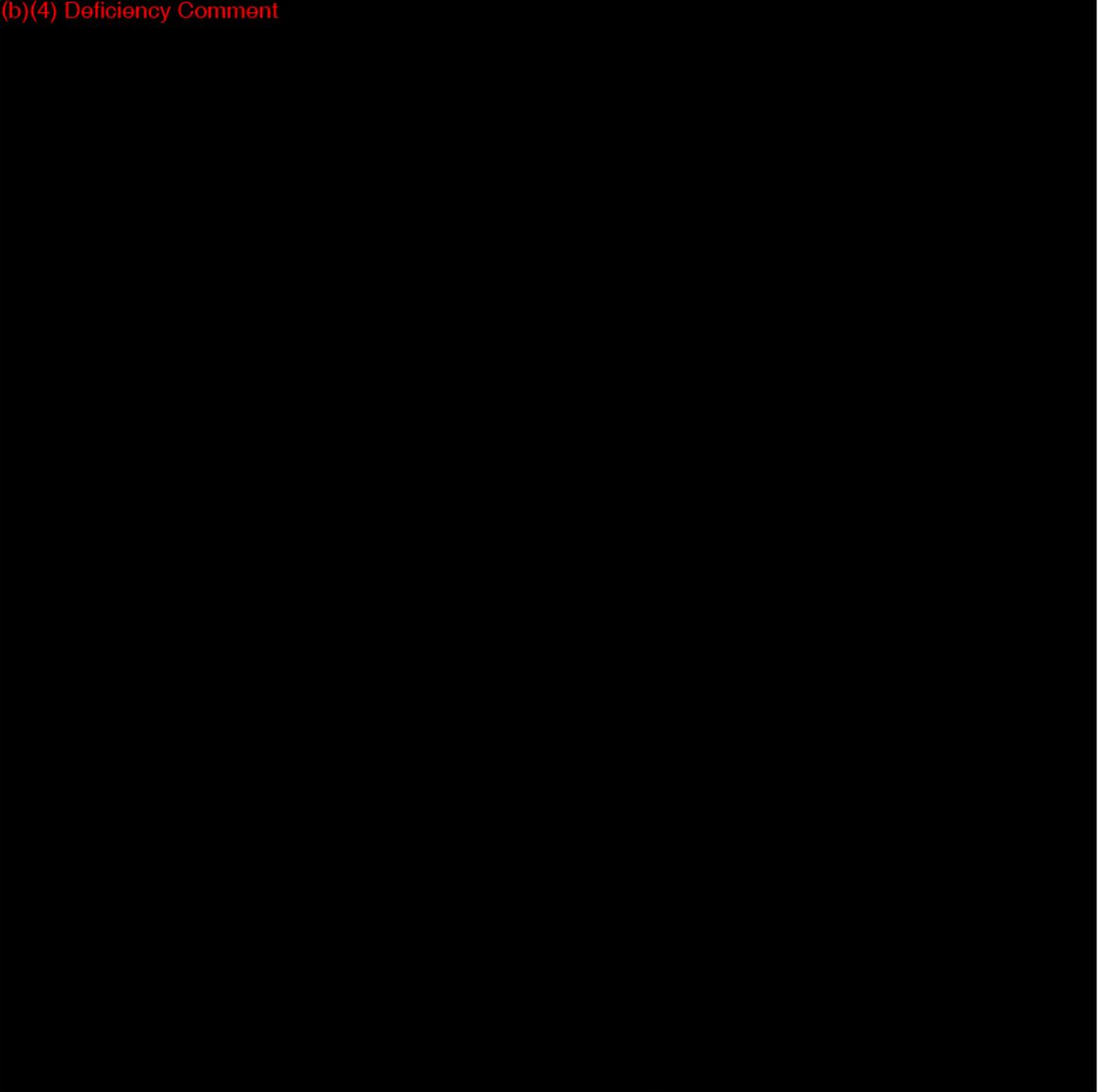
➤ Comment:

Each scope will require separate procodes.

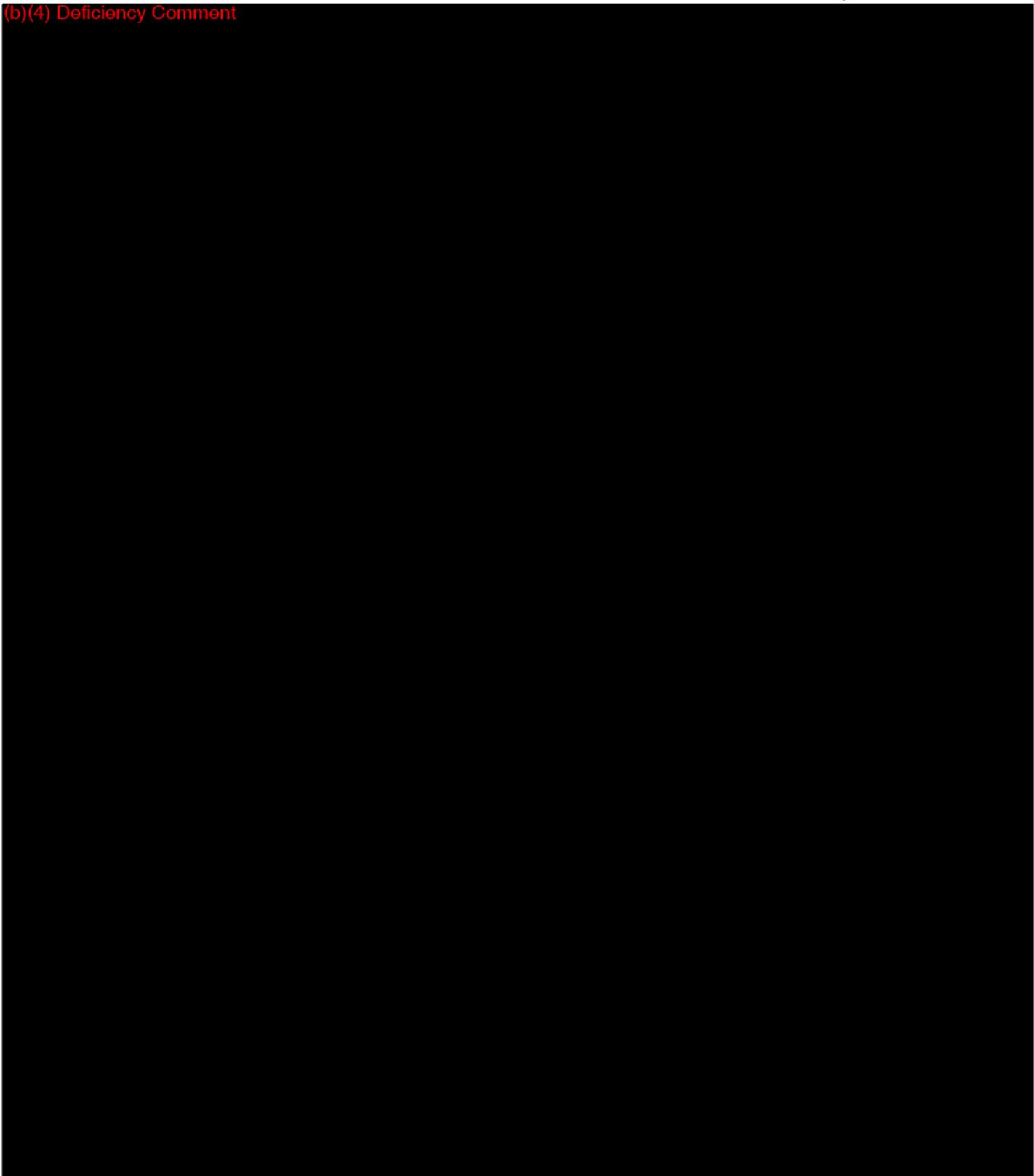
**V. Predicate Device Comparison**

➤ Comment:

(b)(4) Deficiency Comment

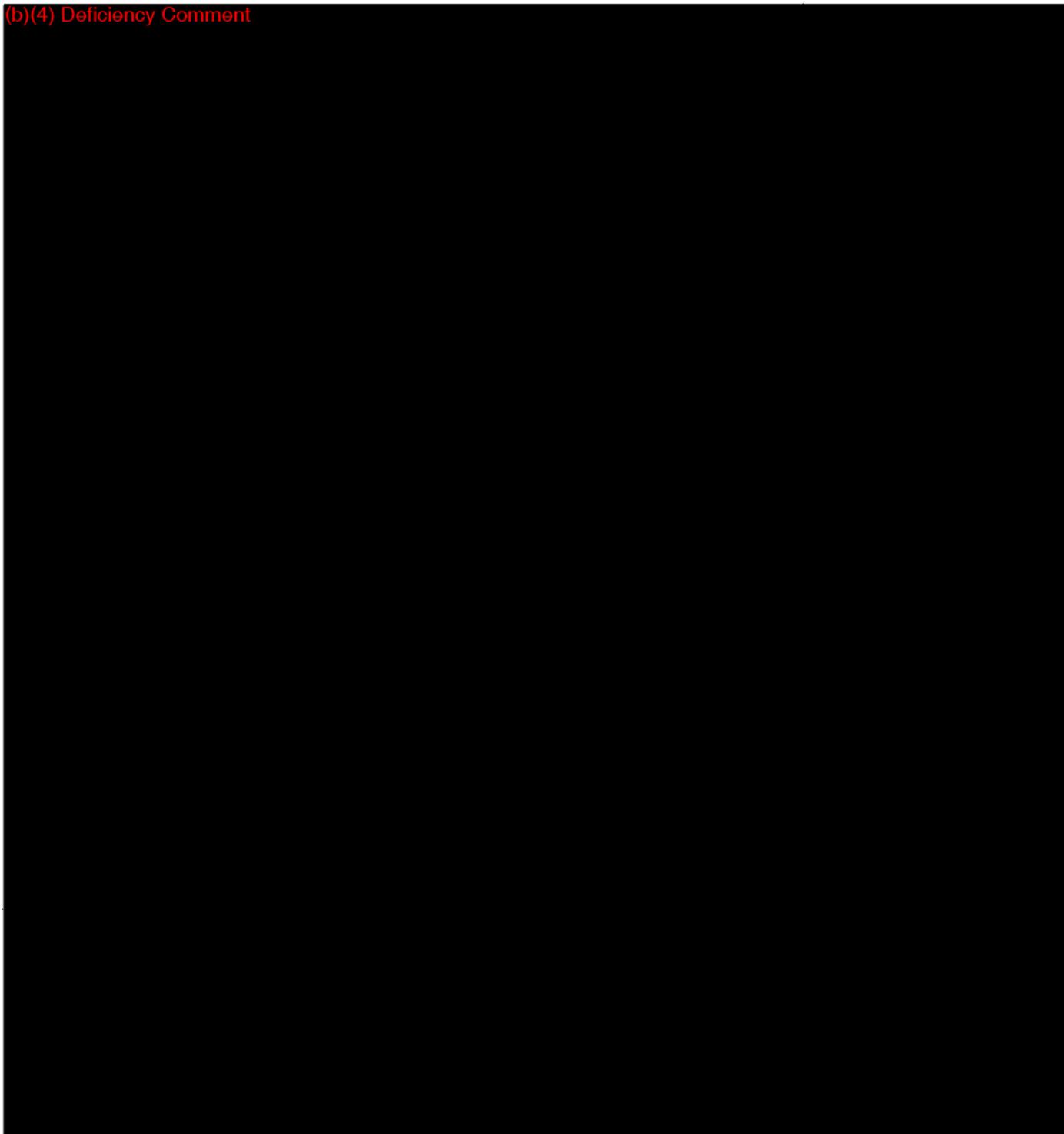


(b)(4) Deficiency Comment



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ProSurg Endoscope  
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(b)(4) Deficiency Comment



**IX. Software**

➤ Comment:

Since the subject device incorporates a digital viewing endoscope with a LED light source and video module interface for display, operating software is needed. The sponsor needs to provide the software evaluation and performance validation according to the following software test requirements.

K120766  
ProSurg Endoscope

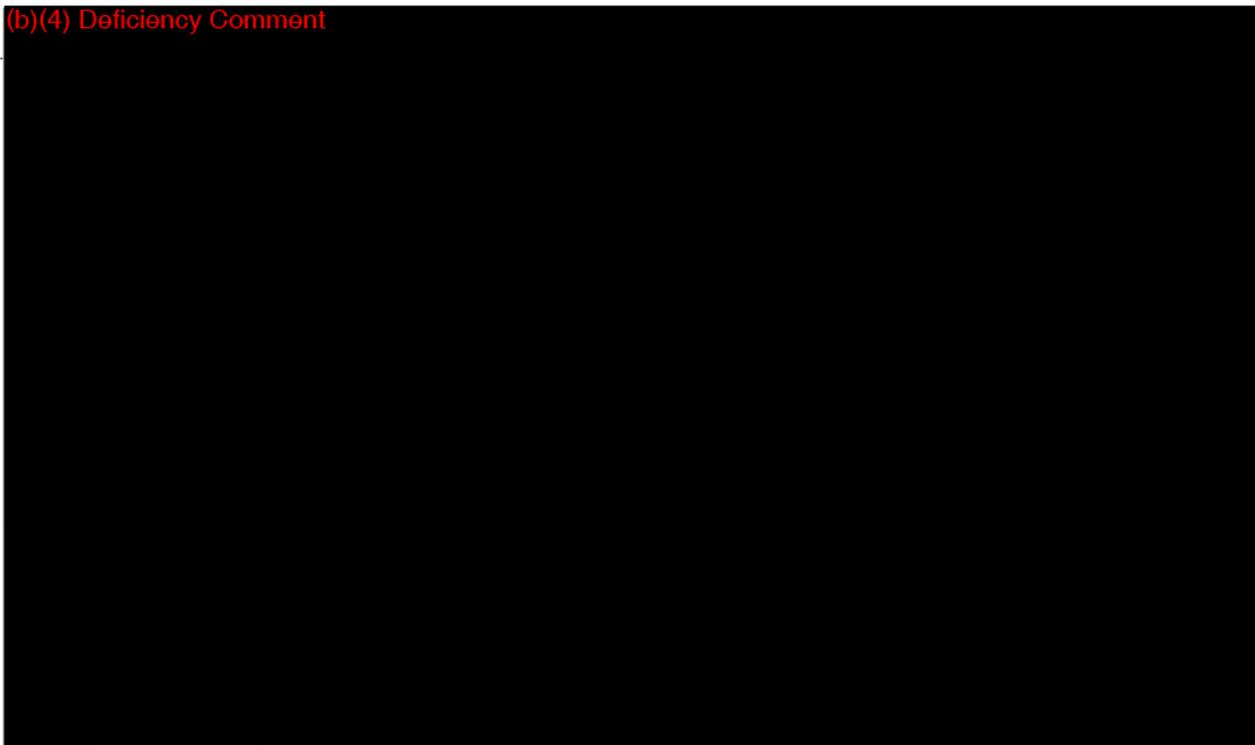
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**Software Test Requirements:**

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices includes the following:

- IEC 62304:2006 Medical Device Software - Software Life Cycle Processes
- <http://www.fda.gov/cdrh/ode/software.html>
- “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf>, 5/11/05
- “Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices”  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073779.pdf>, 9/9/1999
- “General Principles of Software Validation; Final Guidance for Industry and FDA Staff”  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085371.pdf>, 1/11/2002
- “Guidance for Industry. Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software”  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf>, 1/14/05

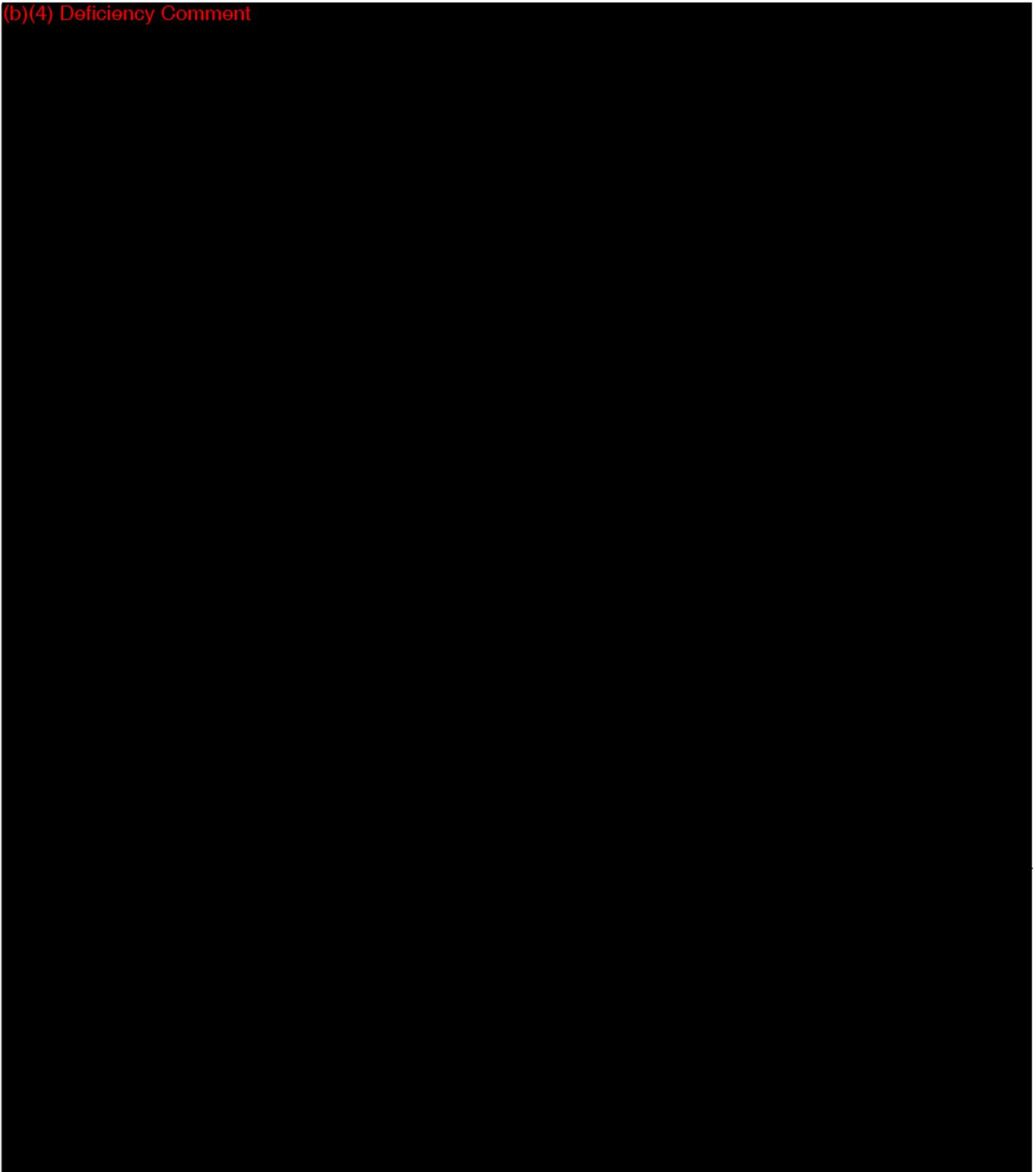
(b)(4) Deficiency Comment



K120766  
ProSurg Endoscope

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(b)(4) Deficiency Comment



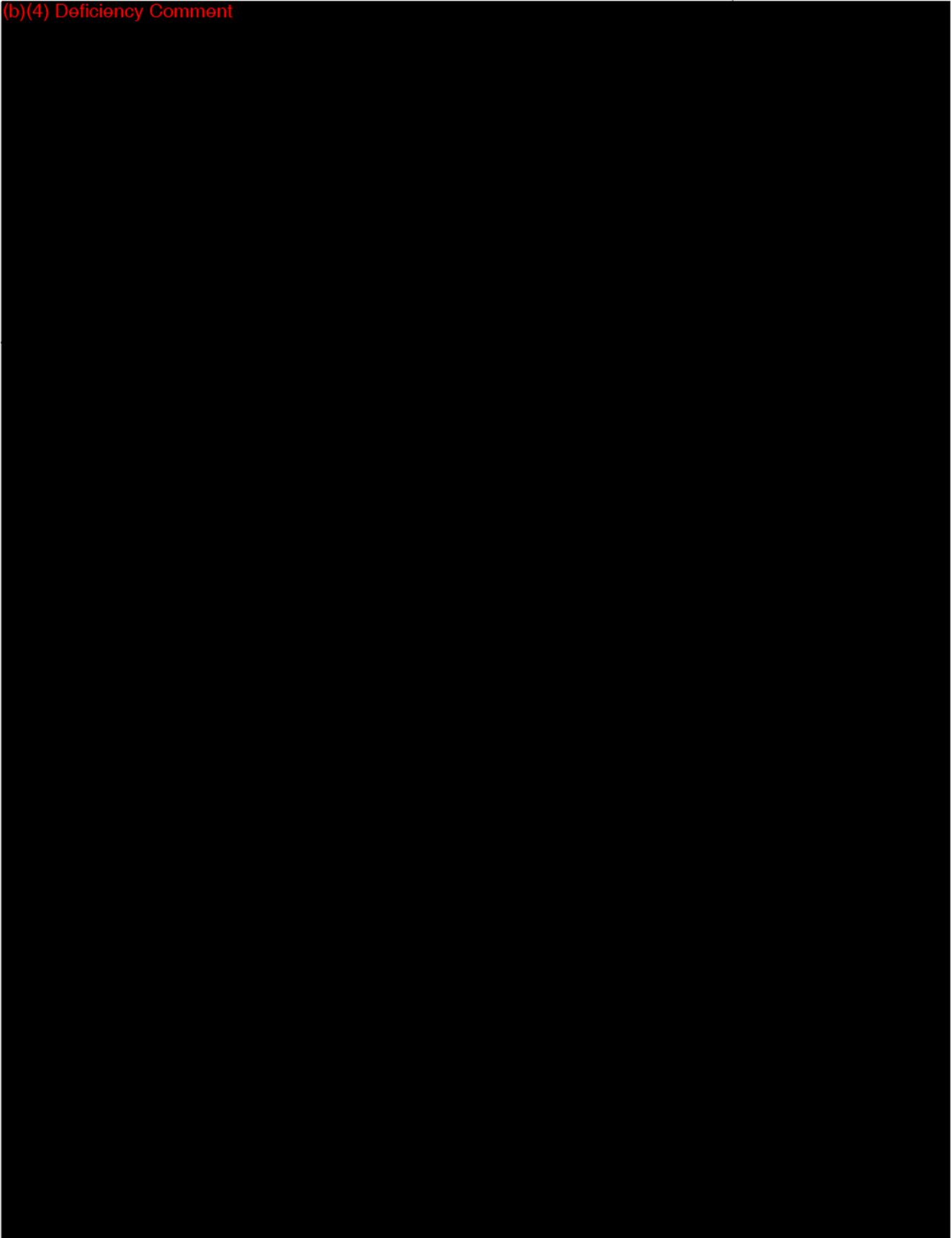
**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

➤ Comment:

**Electromagnetic Compatibility**

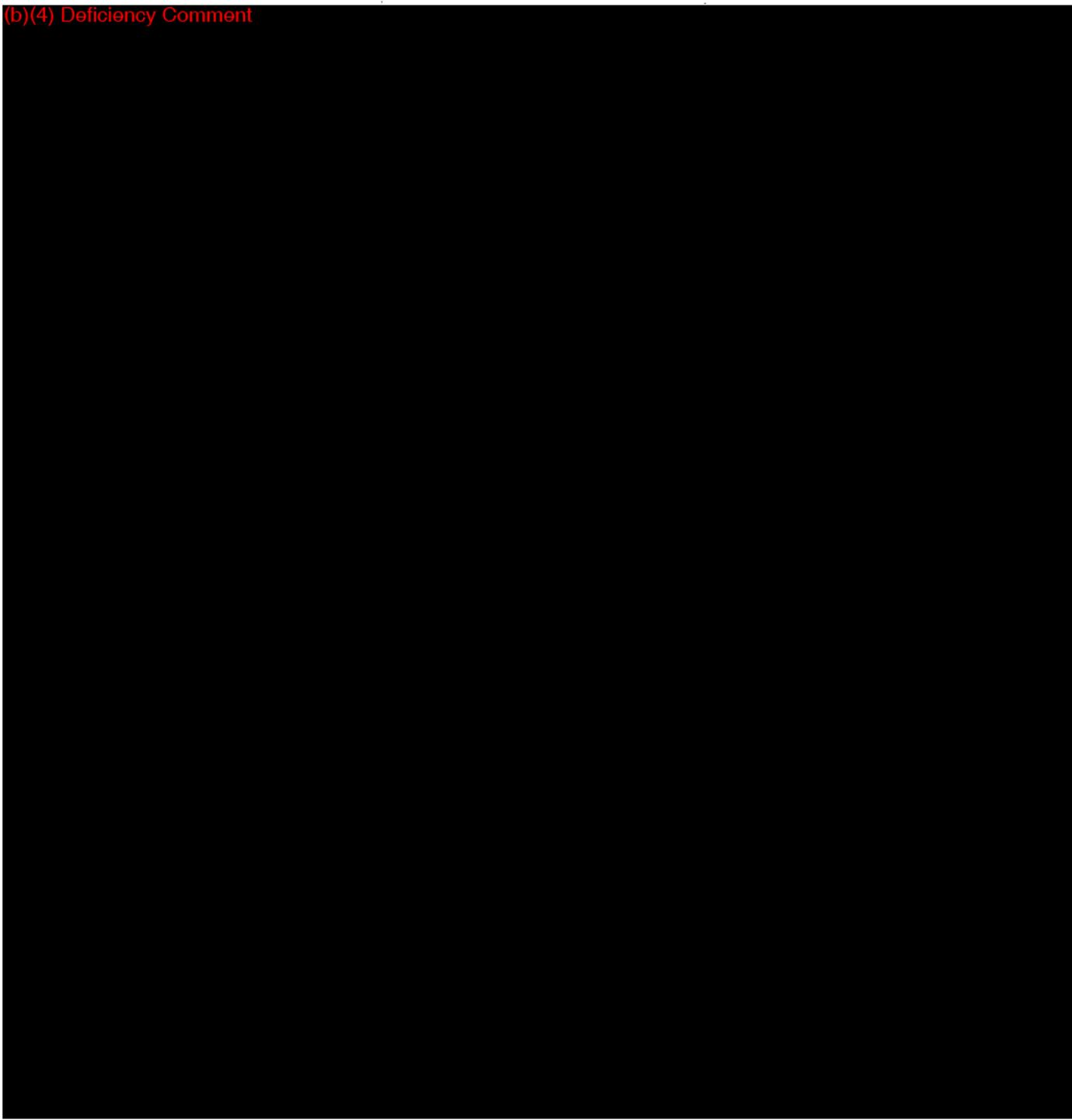
K120766  
ProSurg Endoscope  
8

(b)(4) Deficiency Comment



K120766  
ProSurg Endoscope  
9

(b)(4) Deficiency Comment



**XII. Performance Testing – Animal**

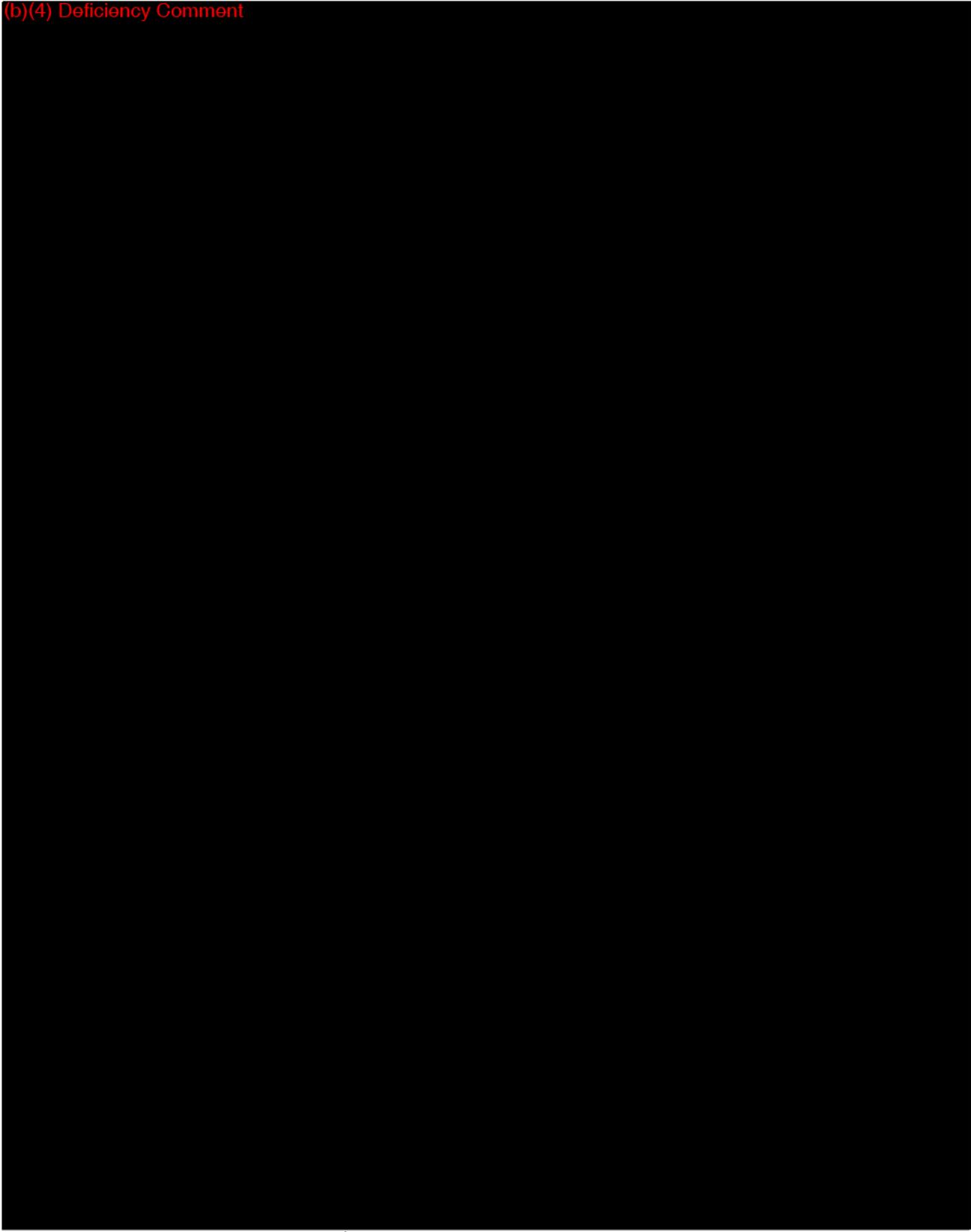
There are no animal testing requirements for this device.

**XIII. Performance Testing – Clinical**

There are no clinical testing requirements for this device.

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(b)(4) Deficiency Comment



K120766  
ProSurg Endoscope  
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Questions? Contact FDA/CDRH/OCE/DID at [CDRH-FOISTATUS@fda.hhs.gov](mailto:CDRH-FOISTATUS@fda.hhs.gov) or 301-796-8118

(b)(4) Deficiency Comment



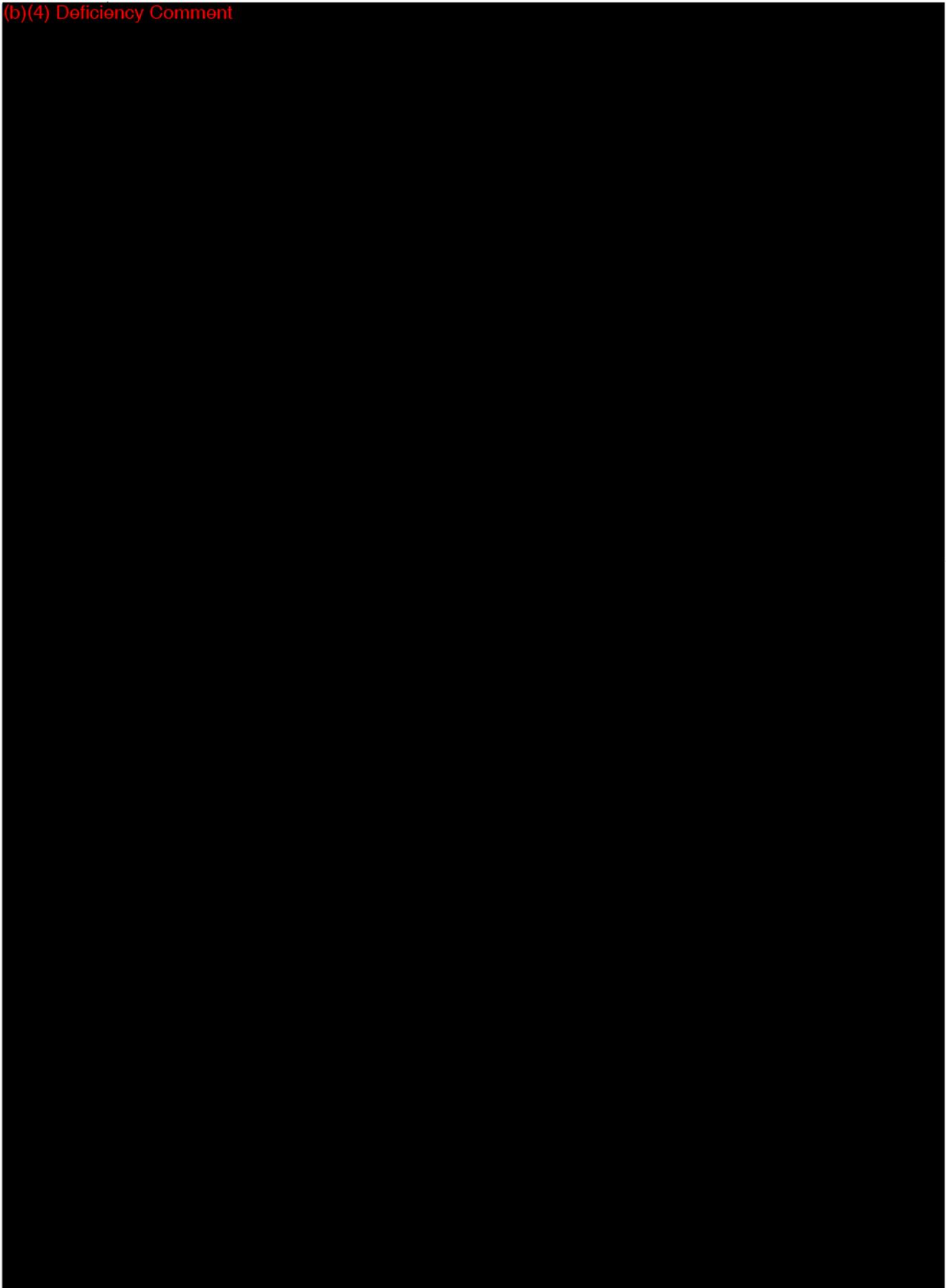
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K120766  
ProSurg Endoscope

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

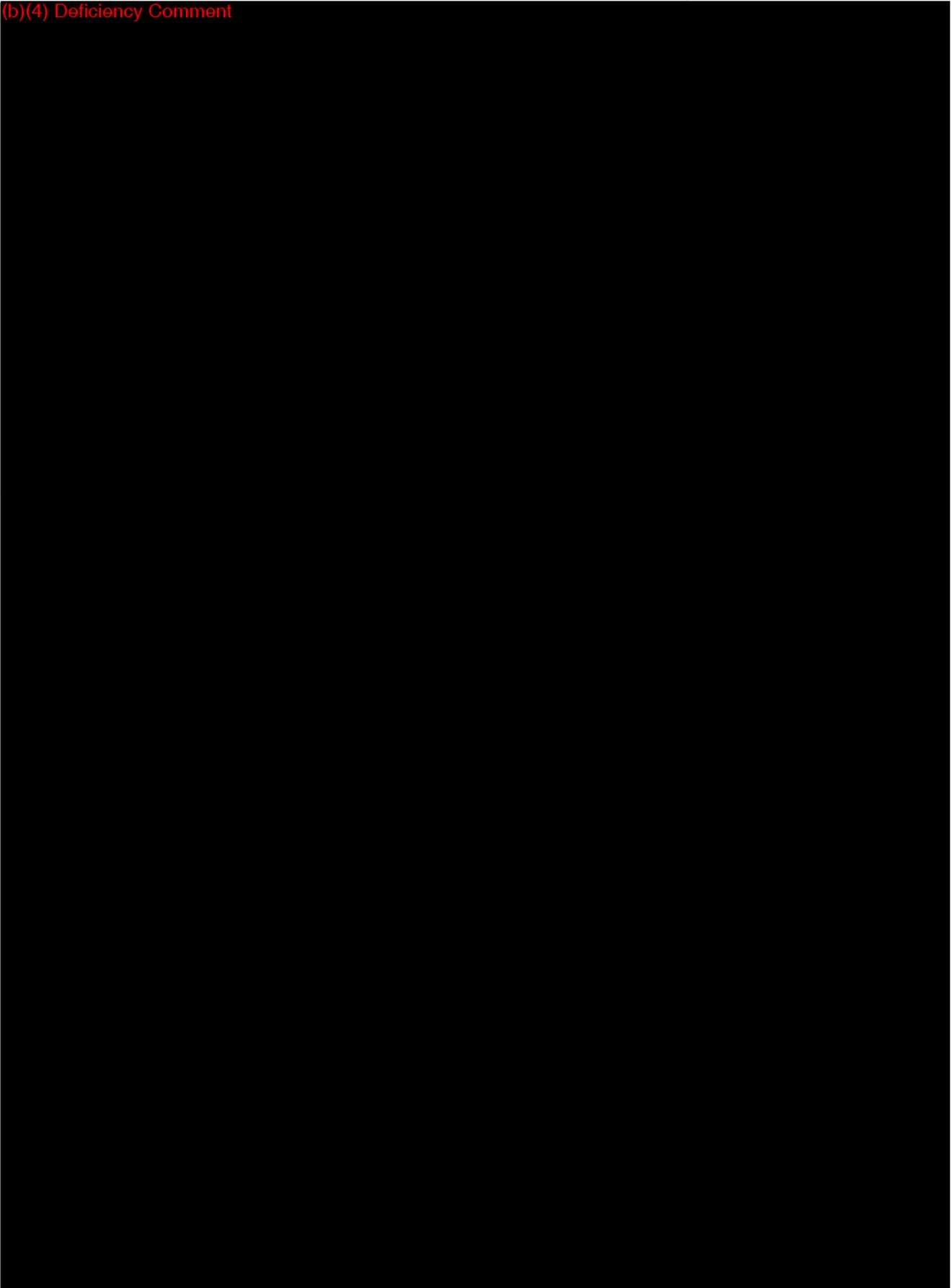
(b)(4) Deficiency Comment



K120766  
ProSurg Endoscope  
13

Questions? Contact FDA/CDRH/OCE/DID at [CDRH-FOISTATUS@fda.hhs.gov](mailto:CDRH-FOISTATUS@fda.hhs.gov) or 301-796-8118

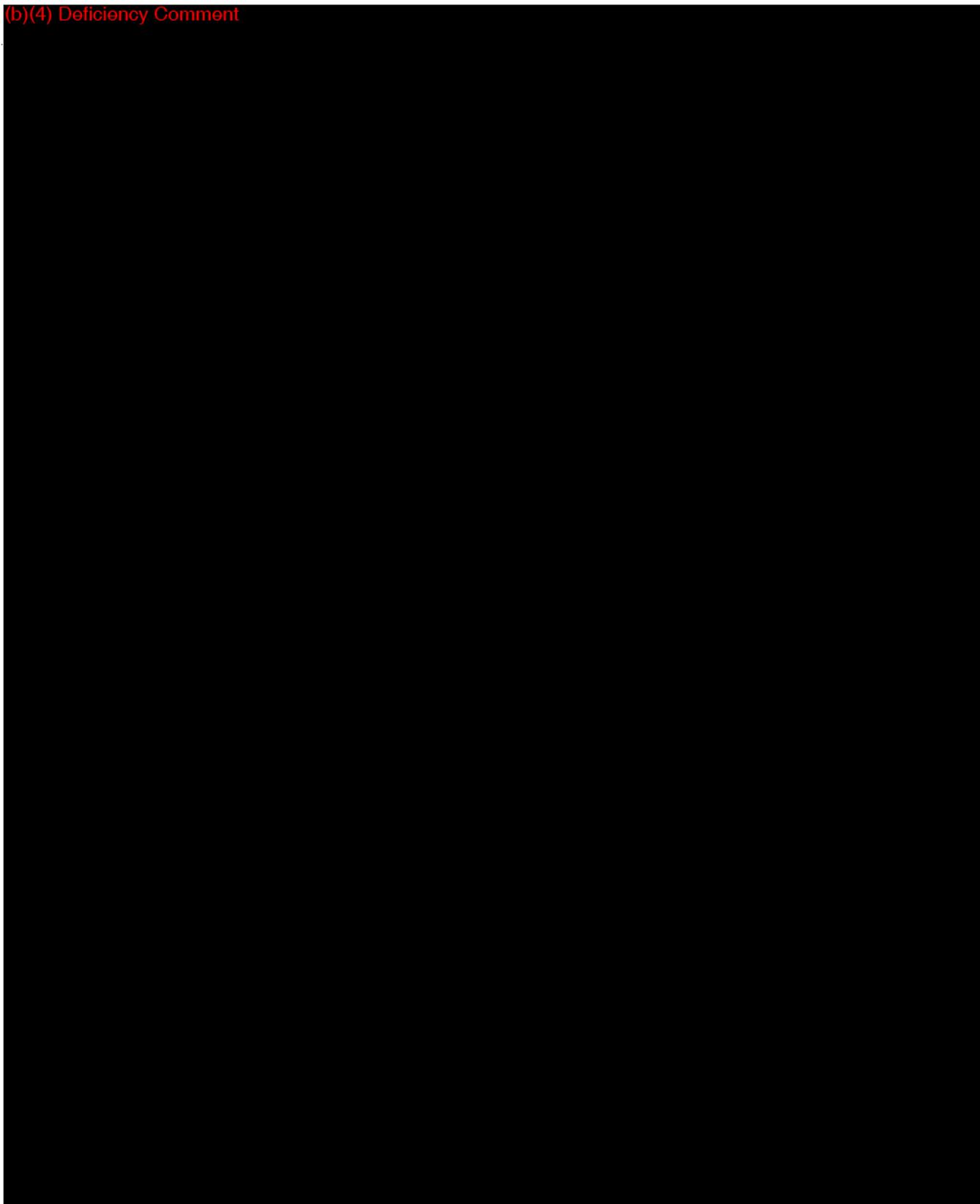
(b)(4) Deficiency Comment



K120766  
ProSurg Endoscope  
14

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

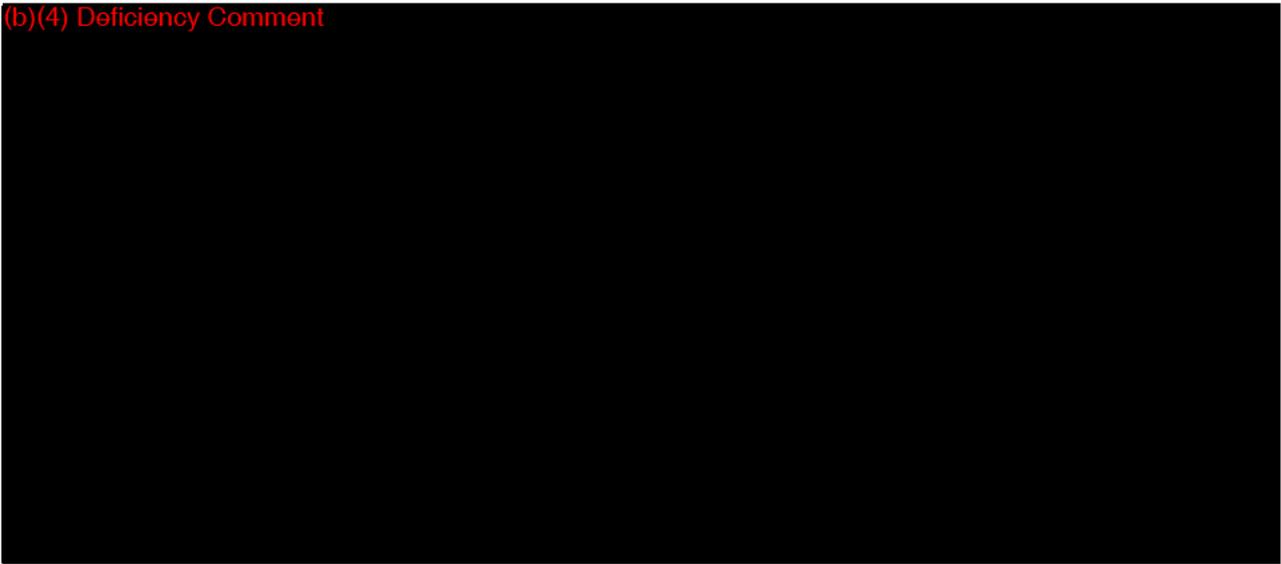
(b)(4) Deficiency Comment



K120766  
ProSurg Endoscope  
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Questions? Contact FDA/CDRH/OCE/DID at [CDRH-FOISTATUS@fda.hhs.gov](mailto:CDRH-FOISTATUS@fda.hhs.gov) or 301-796-8118

(b)(4) Deficiency Comment



**XVI. Contact History**

**K120766 dated 5 March 2012 received 8 May 2012**

**XVII. Recommendation: AI**

Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: Class II  
Product Code: FAJ

Reviewer

Mary Coburn Ruden  
MB - Bill  
Branch Chief

Date

25 June 2012  
25 June 2012  
Date



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**MEMORANDUM**

Food and Drug Administration  
Office of Device Evaluation  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

**Engineering Consult**

**K120766**

Date: June 26, 2012

To: Mary Beth O'Brien

From: Tuan Nguyen

CC: Glenn Bell

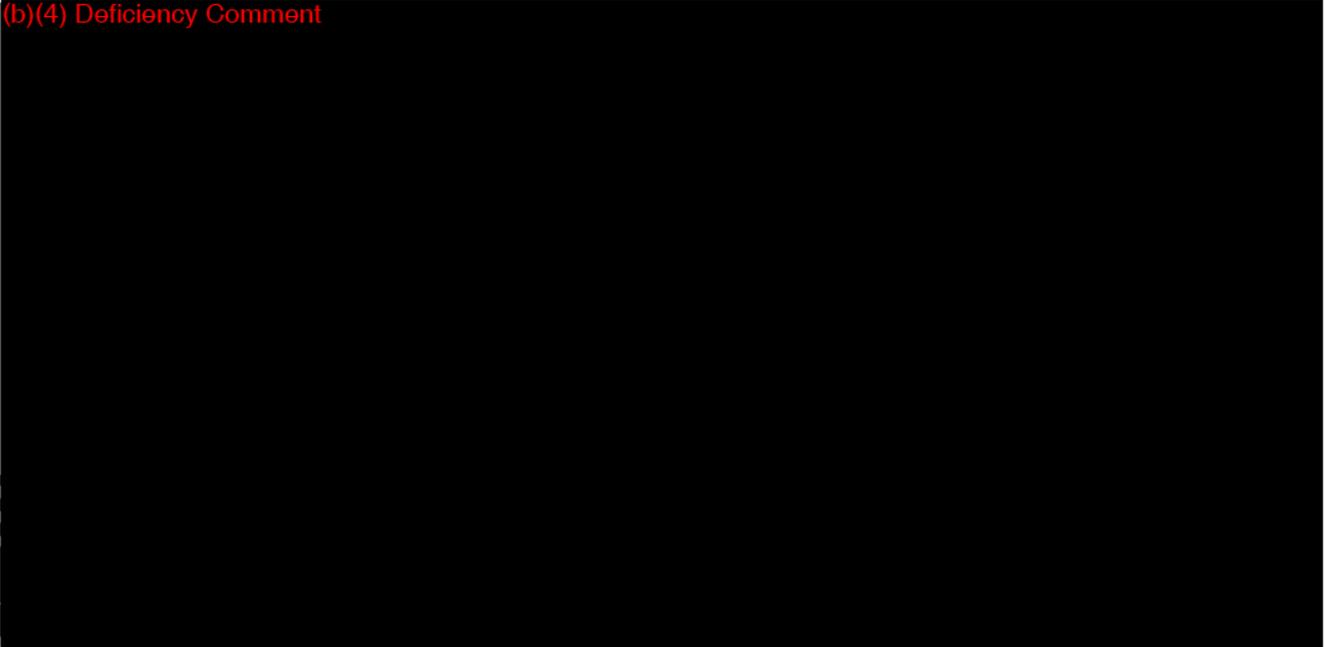
510(k) Holder: ProSurg, Inc.

Device Name: NeoScope™ Endoscopic Diagnostic & Treatment System (Modification)

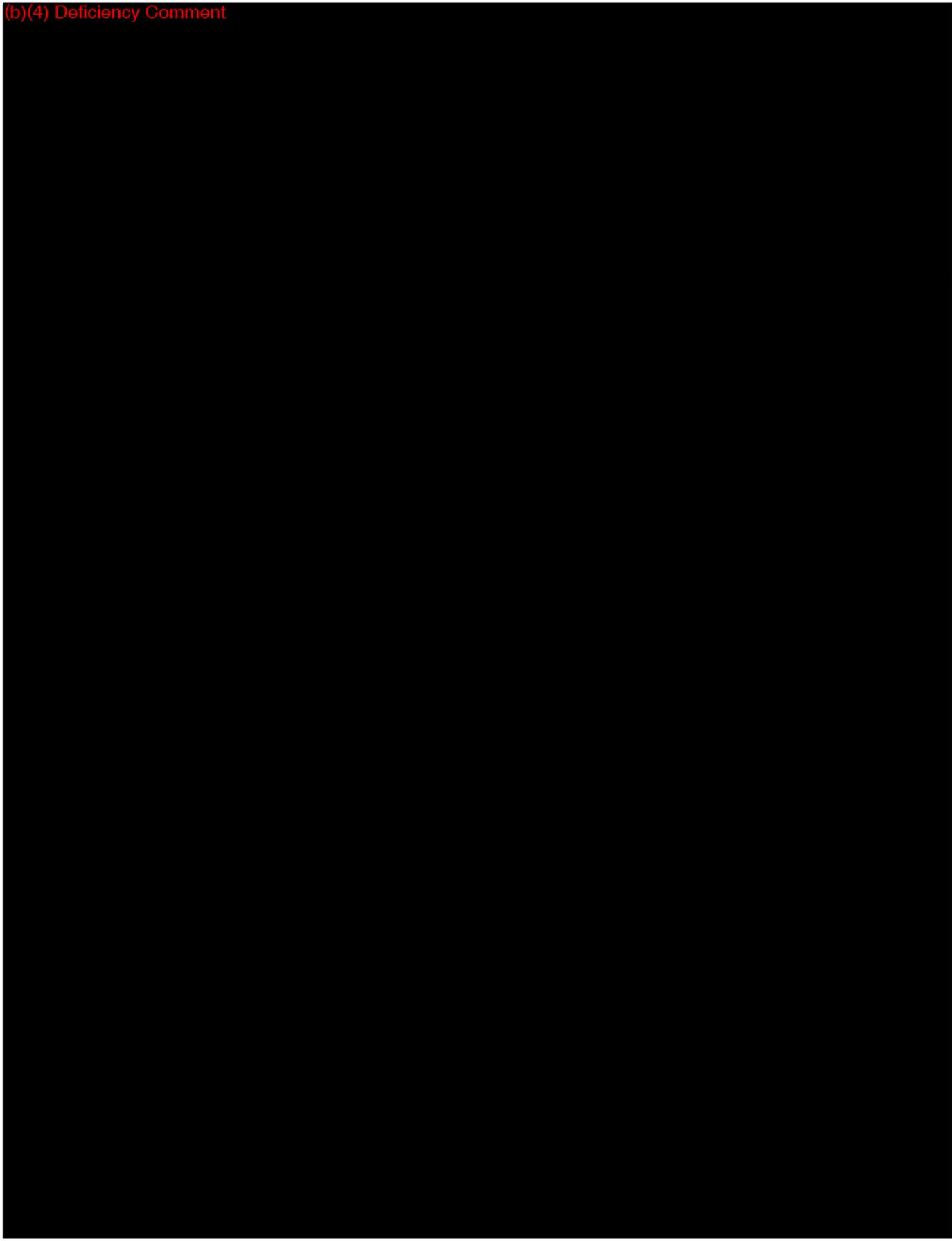
**I. Purpose and Summary**

Per your request, I have reviewed this 510(k) with emphasis on the engineering aspect of the submission.

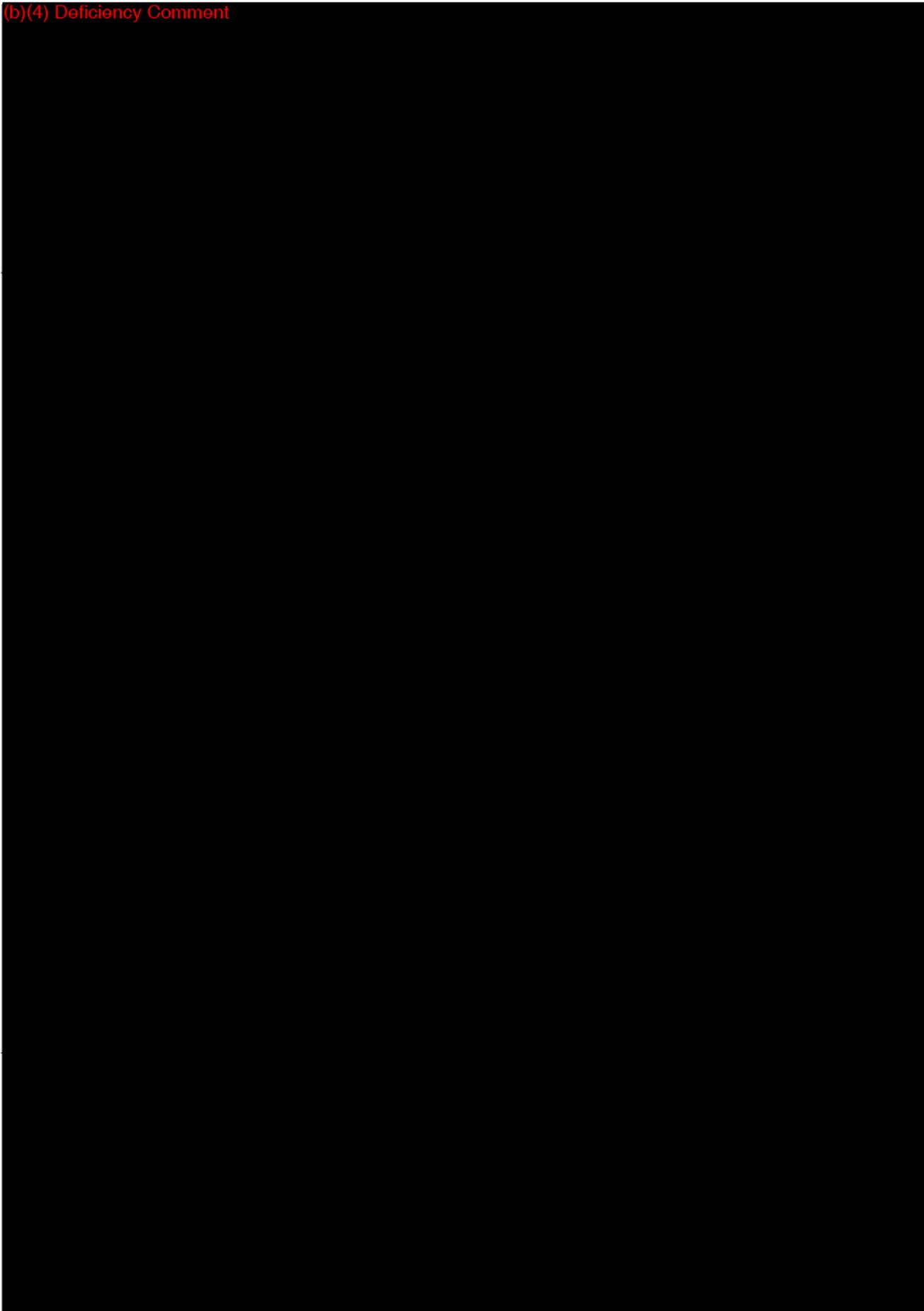
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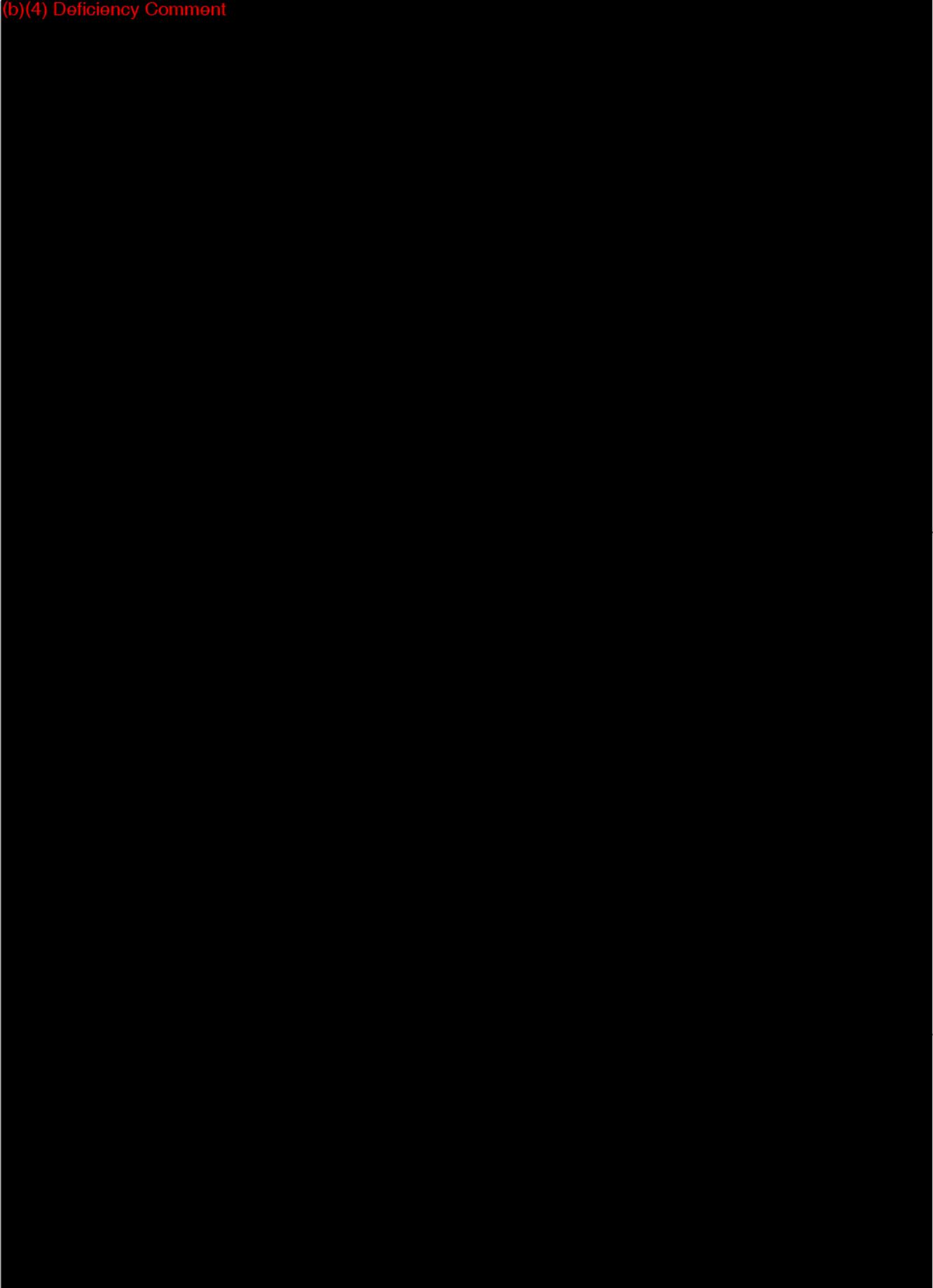
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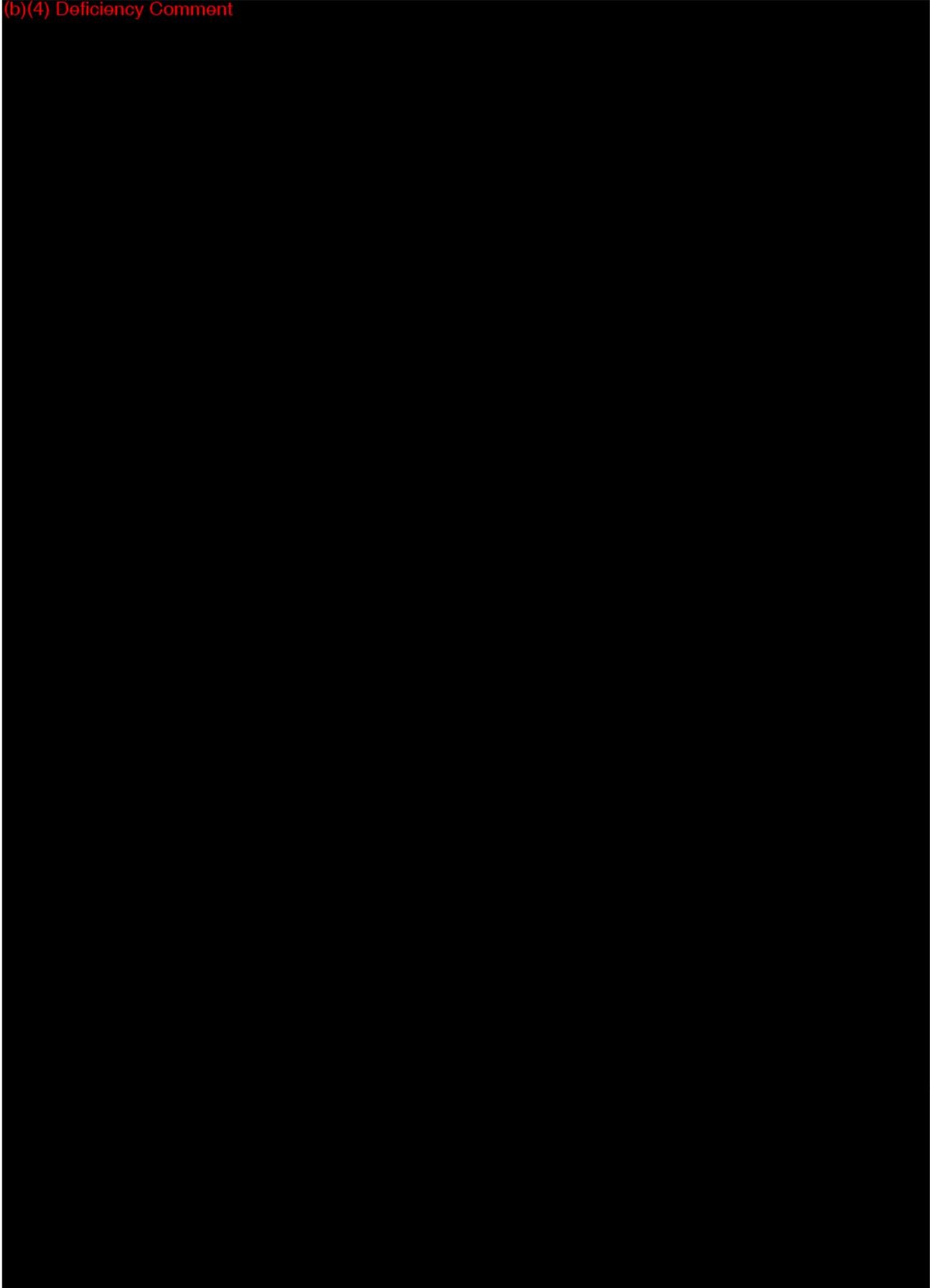
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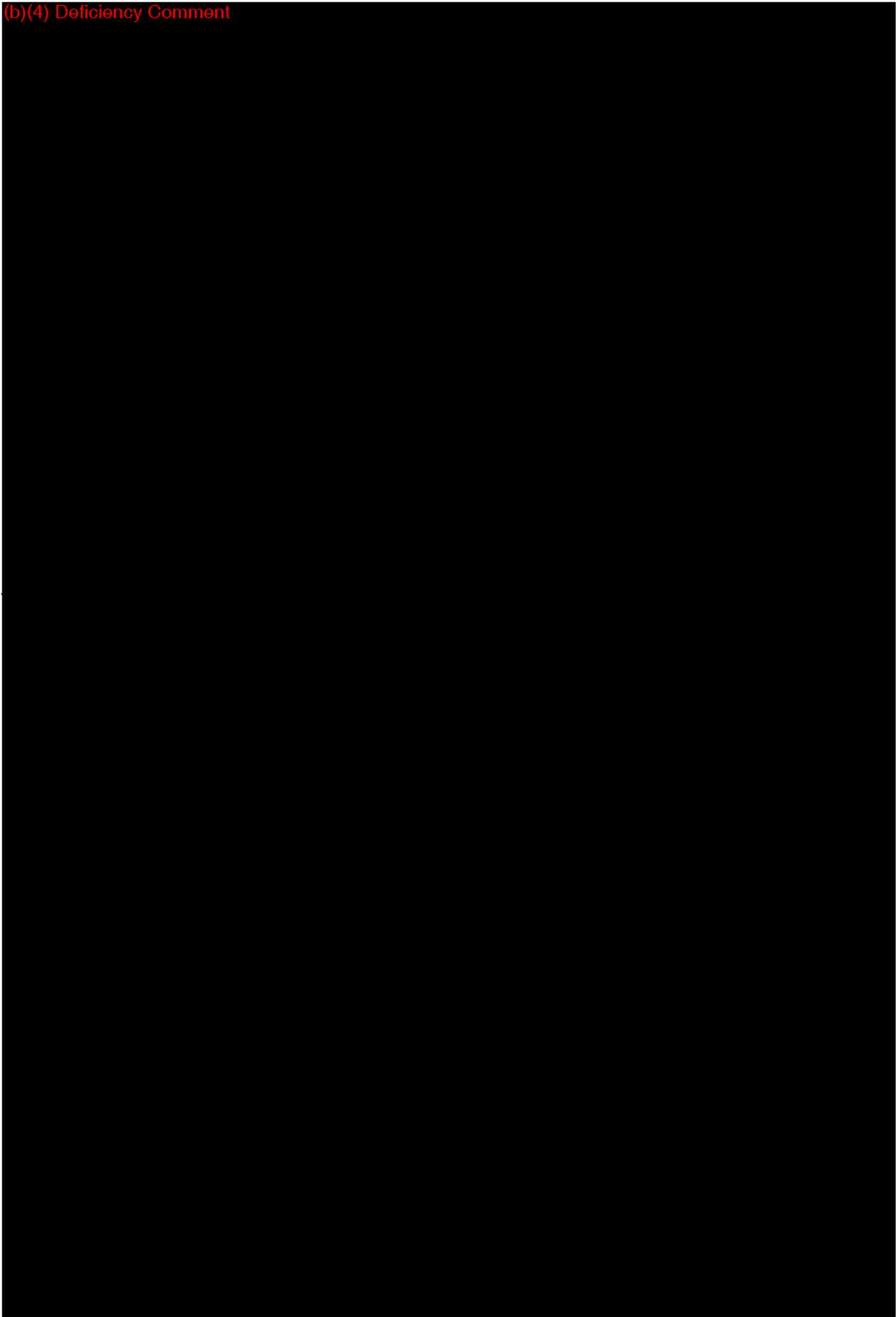
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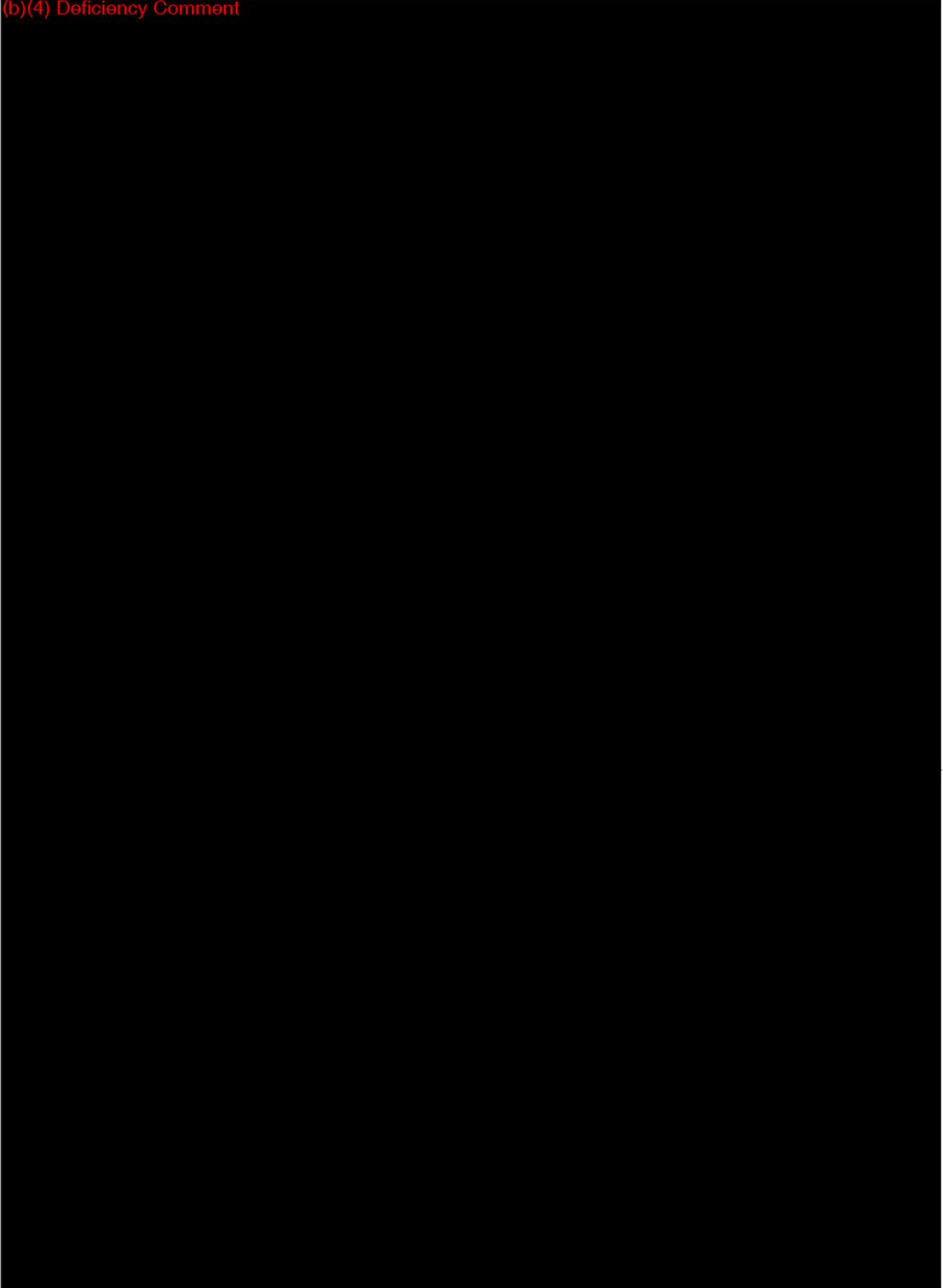
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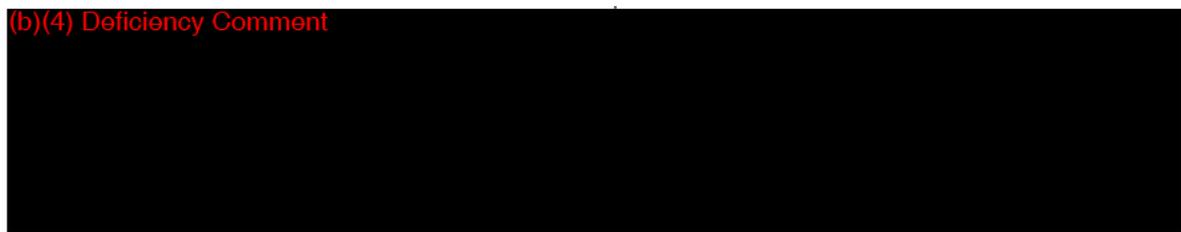
(b)(4) Deficiency Comment



(b)(4) Deficiency Comment



(b)(4) Deficiency Comment



Tuan Nguyen, Ph.D.



U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

May 09, 2012

PROSURG, INC.  
2195 TRADE ZONE BLVD.  
SAN JOSE, CALIFORNIA 95131  
ATTN: A. DESAI

510k Number: K120766

Received: 5/8/2012

Product: ENDOSCOPIC DIAGNOSTIC & TREATM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

**Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.**

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

**Nichols, Karl \***

---

**From:** Microsoft Outlook  
**To:** 'ashvin@prosurg.com'  
**Sent:** Tuesday, March 13, 2012 4:16 PM  
**Subject:** Relayed: K120766- Acknowledgement Letter

**Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:**

'ashvin@prosurg.com'

Subject: K120766- Acknowledgement Letter

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Sent by Microsoft Exchange Server 2007



U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

March 13, 2012

USER FEE HOLD LETTER - HAVE NOT RECEIVED PAYMENT

PROSURG, INC.  
2195 TRADE ZONE BLVD.  
SAN JOSE, CALIFORNIA 95131  
ATTN: A. DESAI

510k Number: K120766

Received: 3/13/2012

User Fee ID Number:

Product: ENDOSCOPIC DIAGNOSTIC &

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to mail a check, please send a check to one of the addresses listed below:

By Regular Mail  
Food and Drug Administration  
P.O. Box 956733  
St. Louis, MO 63195-6733.

By Private Courier(e.g., Fed Ex, UPS, etc.)  
U.S. Bank  
956733  
1005 Convention Plaza  
St. Louis, MO 63101

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301)847-8120 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at [www.fda.gov/cdrh/mdufma/fy09userfee.html](http://www.fda.gov/cdrh/mdufma/fy09userfee.html). In addition, the 510k Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Records Released under FOIA request 2015-10055. Released by CDRH on 07/08/2016.  
In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm>.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)796-7100 or its toll-free number (800)638-2041, or contact them at their Internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Edwena Jones at [Edwena.Jones@fda.hhs.gov](mailto:Edwena.Jones@fda.hhs.gov) or directly at (301)796-7200. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Edwena Jones  
Consumer Safety Technician  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and Radiological Health

K120766



March 5, 2012

To: Director, Food and Drug Administration.  
Urology and Lithotripsy Devices Branch  
Division of Reproductive, Abdominal & Radiological Devices.  
Office of Device Evaluation / CDRH  
Document Mail Center (HFZ-401)  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-002

FDA CDRH DMC  
MAR 13 2012  
Received K7

Re.: **510(k) Premarket Notification:**

**NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification )**

Dear Sir,

Pursuant to 21 CFR 820.90, enclosed please find a copy of 510k Premarket Notification applications for the above named devices for your review.

The use of the term “substantially equivalent,” “similar” and other related terms and descriptions in this notification comparing *NeoScope™*- Endoscopic Diagnostic & Treatment System (Modification) to the predicate devices are made only to meet the requirements of the Federal Food, Drug and Cosmetic Act as amended and regulations there under, and for no other purpose.

The NeoScope™- Endoscopic Diagnostic & Treatment System (Modification) is substantially equivalent to the predicated device NeoScope™- Endoscopic Diagnostic & Treatment System from ProSurg Inc, cleared by FDA under 510k application K# 042780 on Feb 3, 2005. The only modification to the NeoScope Endoscopic System is to include the use of Digital endoscope device with CMOS sensor & LED module instead of a conventional “Rod lens” and “fiber optic” viewing endoscope and light source. As we all know, currently the CMOS / CCD Imaging sensor with LED represents a proven technology for endoscopic viewing and illumination of the target body organ. The Proposed NeoScope Endoscope device ( Rigid & Flexible ) is designed to be compatible with all the components of the Original NeoScope system, including an Outer guide probe (Sheath) , Bridge adapters and accessories . The NeoScope system (modification) is also designed for Single Use, thus minimizing risk of cross contamination and infections.

Please review the attached application and let us know if you need additional details or clarification.

Thank you and Best Regards,

A. Desai, Manager, Regulatory Affairs

ProSurg,  
2195 Trade Zone Blvd

San Jose CA 95131

Tel 408 945 4044 / Fax 408 945 1390, E mail: [ASD@prosurge.com](mailto:ASD@prosurge.com) Inc

2193 Trade Zone Blvd. San Jose, CA 95131

Tel: (408) 945-4044, 1-800-200-SURG Fax: (408) 945-1390

Questions? Contact FDA/CDRH at [CDRH@FDA.gov](mailto:CDRH@FDA.gov) or 301-796-8118

PROSURG, INC

**510 (k) Application**

**NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification )**

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**510 (k) Notification**

Date: March 5, 2012

**Device Proprietary Name:** *NeoScope*™- Endoscopic Diagnostic & Treatment System ( Modification )

**Device Common, Usual or Classification Name:** Endoscope and Accessories Flexible / Rigid

**Product Code:** FAJ and FGA

**Division /Subsidiary Name:** Prosurg, Inc

**Est. Regis No.** 2939814

Notification for  New Device  Significant change/modification  Change in int. use

**Classification Panel Name:** Division of Reproductive, Abdominal & Radiological Devices / CDRH

Pursuant to 21 CFR Part 876 .1500 this device is:

Class I  Class II  Class III

Not Classified- the following provides the basis for this determination: N/A

Pursuant to Section S14 of the Act and 21 CFR part 861, the following action has been taken to assure performance to he appropriate performance standards:

Not Applicable  No standard(s) presently exist for this device

- The following performance standards apply and are being complied with: 21CFR Part 878.4300

The following is attached, where appropriate, in support of this 510k notification:

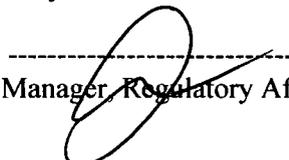
- Labels, labeling, advertisements, and/or directions
- Finished product photographs and engineering drawings
- Statement and data supportive of similarity/differences of comparable product types in distribution.

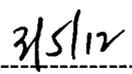
Supportive data in consideration of consequences and effects of a chance or modification as related to safety and effectiveness including a detailed description of the significant change/modification.

Supportive data in consideration of consequences and effects as related to a new use of the device including a detailed description of the new intended.

**Confidentiality if intent to market:**  Applicable  Not Applicable

Submitted by: A. Desai

Title:  Manager, Regulatory Affairs

  
Date

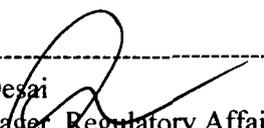
Prosurg, Inc  
2195 Trade Zone Blvd  
San Jose CA 95131

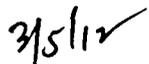
**Premarket Notification 510 (k) Statement  
(As required by 21 CFR 807.93)**

**NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification )**

I certify that as Manager of Regulatory Affairs of Prosurg, Inc, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent.

The information I agree to make available will be duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade and confidential commercial information, as defined in 21 CFR 20.61.

-----  
  
A. Desai  
Manager, Regulatory Affairs  
Prosurg, Inc  
San Jose CA

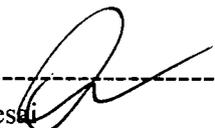
  
March 5, 2012

**Premarket Notification**

**Truthful and Accurate Statement**

**NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification)**

I certify that my capacity as Manager of Regulatory Affairs of Prosurg, Inc., I believe to the best of my knowledge that all data and information submitted in premarket notification are truthful and accurate and that no material fact has been omitted.

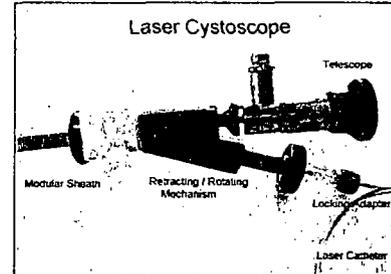
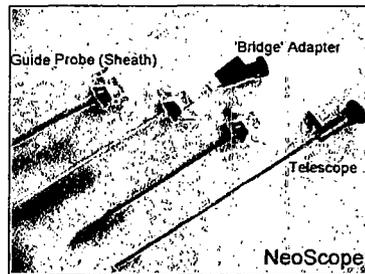
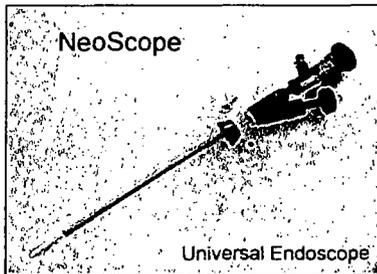
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A. Desai  
Manager, Regulatory Affairs  
Prosurg, Inc  
San Jose CA 95131

3/5/12  
March 5, 2012

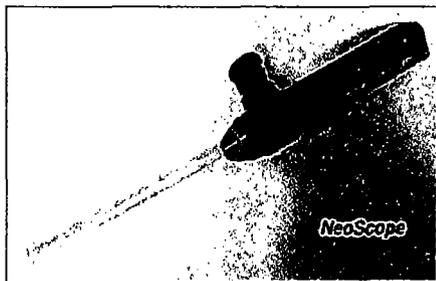
**Product Description:**

**NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification )**

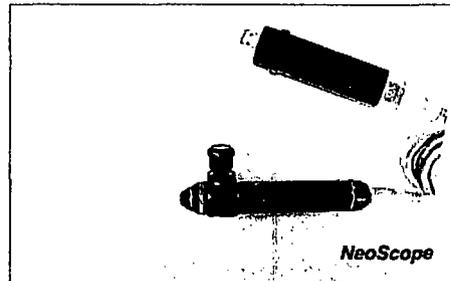
The NeoScope™- Endoscopic Diagnostic & Treatment System is a single use endoscopic diagnostic & surgical treatment device. The NeoScope, a modular endoscopic device is universally compatible with interchangeable components and various endoscopes to provide maximum utility and versatility to physician. The NeoScope endoscopic system consists of an Outer Guide probe (Sheath), connecting “Bridge” adapter, Delivery device and a viewing telescope / endoscope. The NeoScope outer guide probe is designed for continuous irrigation flow and is available in various sizes and configurations including Rigid, Semi-Rigid, Flexible, malleable design made from biocompatible polymer or metal for maximum patient safety and comfort. The Delivery device consists of Injection needle, Catheter or Delivery probes for delivering injectable treatment substance, tissue bulking agents, imaging dyes and contrast agents, drugs, sclerosing agents & bio-toxins. The delivery devices are also designed to deliver thermal energy for tissue ablation and removal using RF ( Monopolar / Bipolar ) , Laser , Microwave energy, Cryo energy and Microsurgical instrumentation. The delivery device can also be used as a Resectoscope, Cystoscope, Ureteroscope, Nephroscope, Hysteroscope, Laparoscope and other endoscopes for tissue treatment including removal and coagulation of tissue using monopolar or bipolar mode of action. The endoscopic device is compatible with commercially available rigid and flexible viewing telescope & endoscopes, marketed by Storz, Wolf, Circon / Gyrus / ACMI, Olympus & others . The NeoScope endoscopic system being modular in design is versatile and can be used as variety of endoscopic configurations including Cystoscope. Resectoscope, Nephroscope, Hysteroscope, Laparoscope for treatment of Urological, Uro-Gynecological , Gynecological and General Surgical disorders.



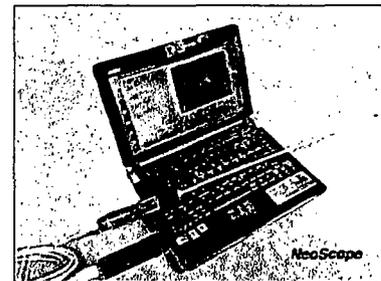
The modification to NeoScope™- Endoscopic System includes the use of a Digital viewing endoscope (Rigid / Flexible) with built-in LED light source and video module interface to a commercially available Laptop / Tablet computer / Smart phone or video Display Monitor. The Digital viewing endoscope incorporates a miniature CMOS (Complimentary Medical Oxide Semi- conductor) imaging sensor and LEDs ( Light Emitting Diodes) located at the distal tip, connecting wires along the length of the rigid or flexible tubular structure, USB connecting cord and a video module interface to a commercially available Laptop / Tablet computer / smart phone or video display monitor. The proposed modification to NeoScope System using digital viewing endoscope can provide maximum utility to physician for endoscopic diagnostic and therapeutic applications of the internal body organs.



NeoScope- Digital endoscope Monitor



NeoScope w / Video Module



NeoScope w / Display

The Digital endoscope is designed to provide optimum visualization using LEDs and excellent image resolution with CMOS sensor of the target tissue. The Rigid /flexible endoscope is also designed with /without a working channel along the length of the endoscope to allow fluid irrigation and microsurgical instrument access, while maintaining clear, unobstructed visualization of the target tissue. The Neoscope can be introduced through various natural body cavities and opening including urinary tract, urethra, bladder, ureter , Kidney, vaginal tract, cervix, uterine cavity, reproductive organs, rectum, GI tract, colon etc or via Percutaneously / Laparoscopically into abdominal cavity for diagnosis and treatment of abdominal body organs. The NeoScope – Digital endoscope design utilizes digital imaging technology and the its materials ,construction is also similar and substantially equivalent to predicate device and commercially available rigid and flexible digital endoscopes marketed by various endoscope companies. The NeoScope endoscope can be used as Cystoscope, Ureteroscopy, Hysteroscope, Laparoscope , Gastroscopy , Nephroscopy and other endoscopes based on its overall diameter, length & working channel dimensions to facilitate easy access to the target body organ during diagnosis & treatment by physician.

The *NeoScope*™ – Digital Endoscope ( Rigid / Flexible) is available as a sterile, single use device , ready to use simply by connecting it to video module and to commercially available computers or Video display monitors including portable Lap Top / Tablet or smart mobile phone.

The Digital Endoscope models are available as Rigid or flexible endoscope and with or without working channel to meet physician's preference.

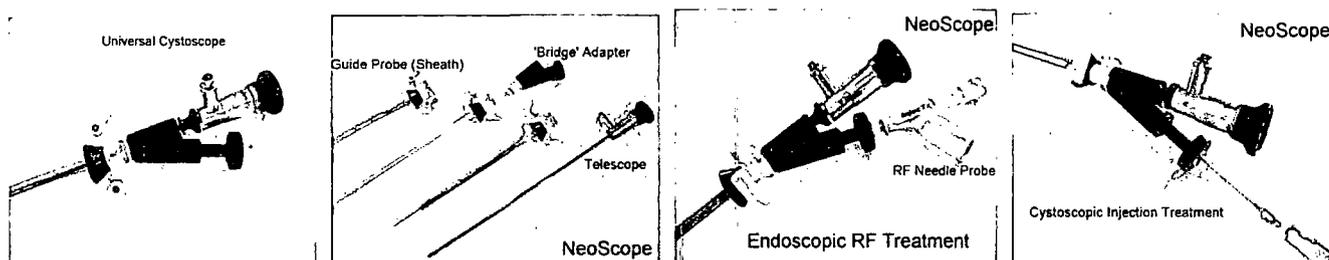
Digital Endoscope Diameter ( Rigid / Flexible )- 4.0, 5.0, 7.0 and 10.0mm  
Digital Endoscope Length: ( Rigid): 15.0, 30.0 and 40.0 cm  
Digital Endoscope Length: (Flexible): 30.0 , 45.0 and 70.0 cm  
Working Channel ( Rigid / Flexible) 1.0mm and 1.5 mm

The NeoScope – Digital Endoscope is also designed to be waterproof, sealed with a clear optical quartz window at the distal end and medical grade TFE outer sheath along the entire length of endoscope tubular structure. The endoscope handle is a made from medical grade ABS polymer with standard USB connector . The Video interface module and USB connecting cables are commercially available and are not patient contact items. The video display monitor devices are also commercially available portable laptop / tablet computers or smart mobile phone.

## Product Configurations:

### NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification )

The product Configuration for NeoScope – Endoscopic Diagnostic & Treatment System ( modification) are as follows:



- (A) Diagnostic & Operative Cystoscope (B) Diagnostic & Operative Laparoscope  
(C) Diagnostic & Operative Resectoscope (D) Diagnostic & Operative Hysteroscope

The Outer Guide Probe / Sheath with Continuous Flow for NeoScope are as follows:

- (A) Rigid Probe / Sheath : (Metal / Plastic ) with Soft Tip
- (B) Flexible Probe / Sheath: (Metal / Plastic ) with Soft Tip
- (C) Semi-Rigid Probe / Sheath : (Metal / Plastic ) with Soft Tip
- (D) Malleable Probe / Sheath : (Metal / Plastic ) with Soft Tip

The Delivery Devices to be used in conjunction with NeoScope System are as follows:

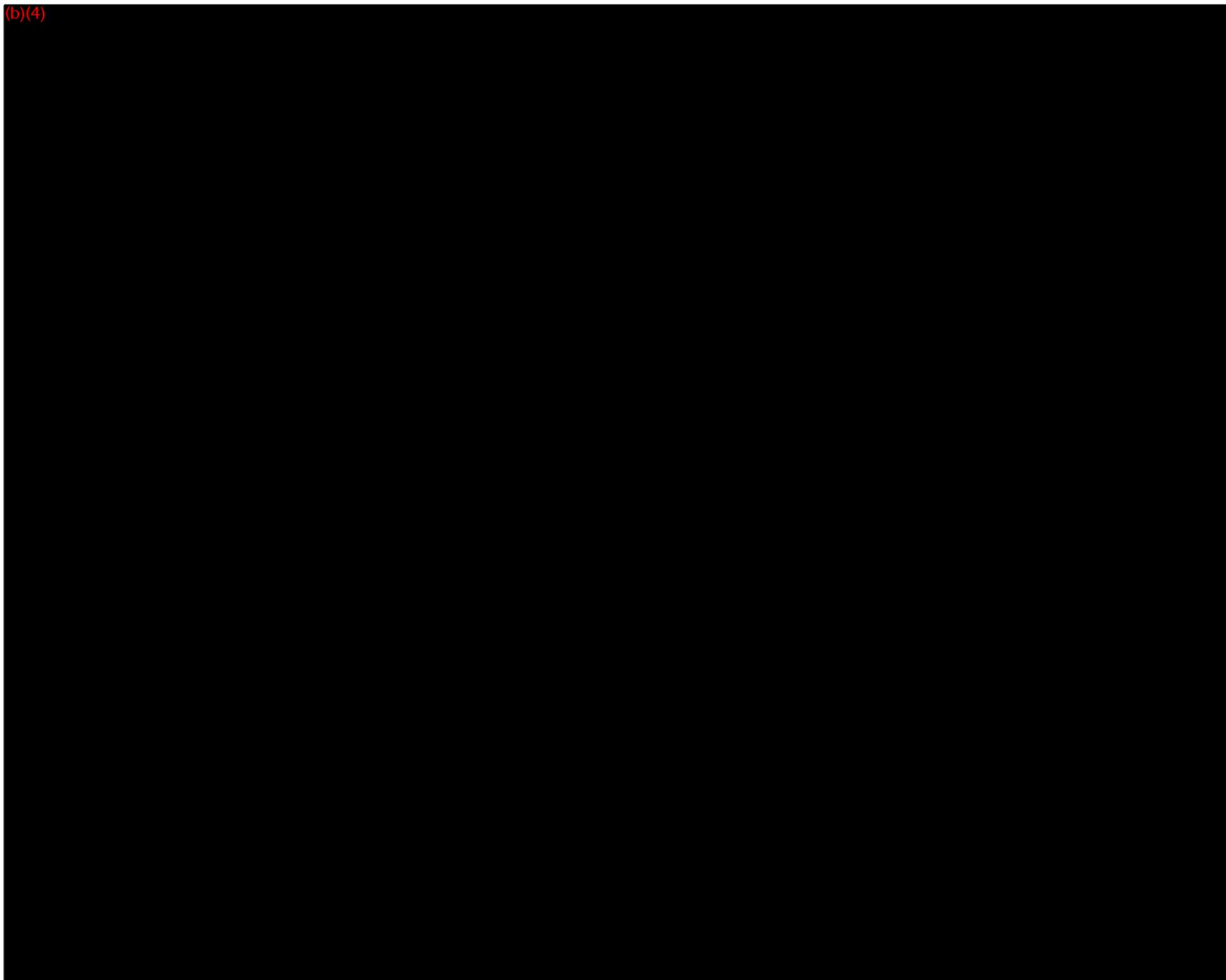
- (A) Endoscopic Injection of agents, dyes, contrast agents, drugs in liquid, solution , viscous gel , mist, semi-liquid, semi–solid or solid material form into target tissue for tissue ablation or treatment under endoscopic visualization.
- (B) Endoscopic Tissue Ablation of target tissue using RF energy probe/ device in monopolar / bipolar or multi polar configuration using Cut, Coag or Vaporization mode of action.
- (C) Endoscopic Tissue Ablation of the target tissue using Laser Fiber optics or catheter using free beam or interstitial treatment mode of action.
- (D) Endoscopic Tissue Ablation device using RF and Laser energy can also be used in conjunction with energy enhancing agents including Hypertonic Saline , Dyes and Photosensitive Chromophores.
- (E) Endoscopic Injection of bulking Agents, polymers, tissue derivatives, cell matrix or other agents into target tissue for tissue bulking or treatment under endoscopic visualization.

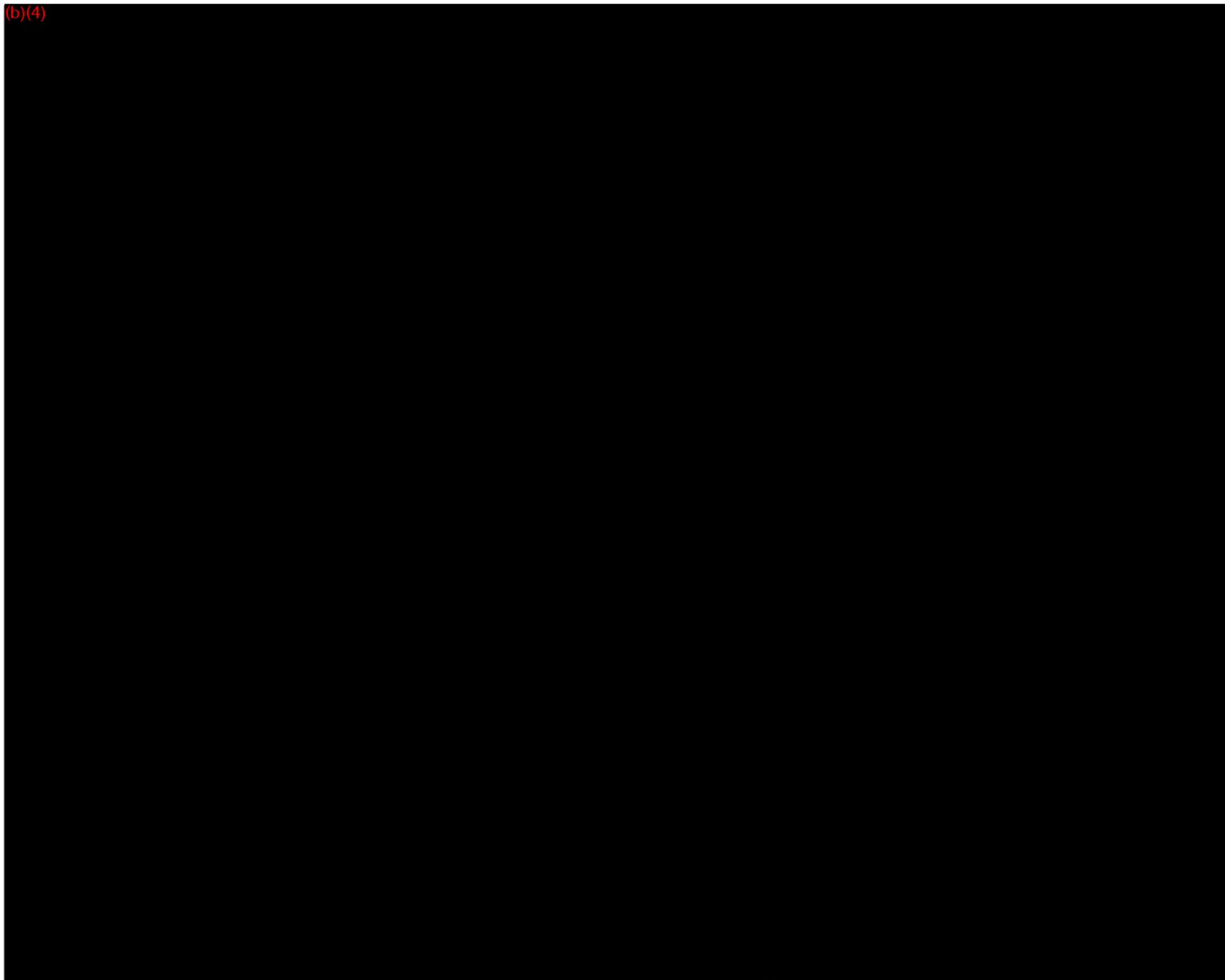
The Viewing endoscope/ telescope that can be used with NeoScope System are as follows:

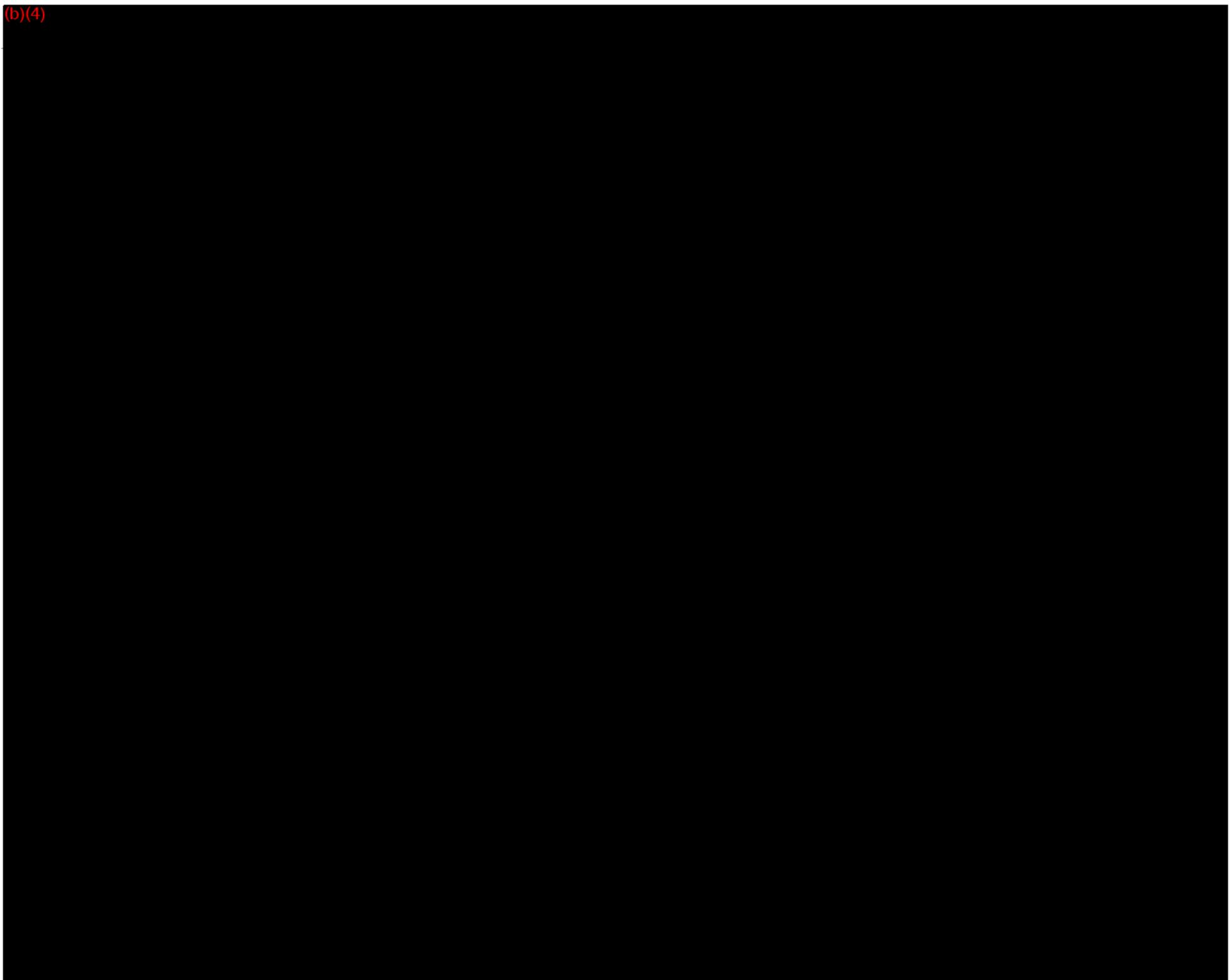
Currently marketed and custom Endoscopes / Telescopes including :

- (A) 2.0mm, 4.0mm,10.0mm diameter & Zero degree , 12 degree & 30 degree Rigid and Flexible endoscopes
- (B) Karl Storz brand
- (C) Olympus brand
- (D) Circon / ACMI / Gyrus brand
- (E) Richard Wolf brand
- (F) Digital Endoscope , Prosurg brand ( NeoScope)

(b)(4)







(b)(4)

(b)(4) Deficiency Comment





(b)(4)

(b)(4)

(b)(4)

## **Product Specifications:**

### **NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification )**

#### **Endoscope Dimensions and Material Specifications:**

##### **(A) Outer Guide Probe ( Sheath ) :**

Diameter : 10 Fr – 36 Fr  
Working Length: 10cm - 45 cm

##### **(B) Delivery Devices:**

Diameter : 3 Fr – 10 Fr  
Working Length: 10cm - 45 cm +/- 0.5cm

##### **( C ) Conventional Viewing Endoscope / Telescope (Rigid / Flexible)**

Diameter : 1.0mm -12mm  
Viewing Angle : 0 degree, 12 degree & 30 degree

##### **(i) Digital Endoscope ( Rigid ) :**

Endoscope Diameter : 5.0 mm , 7.0mm and 10.0 mm  
Endoscope Length: 15 cm , 30 cm and 40 cm  
Endoscope Working Channel: 1.00 mm , 1.5 mm

##### **(ii) Digital Endoscope ( Flexible ) :**

Endoscope Diameter : 5.0 mm , 7.0mm and 10.0 mm  
Endoscope Length: 30 cm , 40 cm and 70 cm  
Endoscope Working Channel: 1.00 mm , 1.5 mm

##### **(iii) Accessories: (Connecting cable & Video Display Monitor) (Non patient contact)**

Video Interface Module: Commercially available video module ( window / Mac OS)

Connecting Cable : Commercially available standard Co-axial video cable , USB Connector

Video Display Monitor : Commercially available Laptop/ Tablet Computer / mobile phone

#### **(C)Material Specifications:**

##### **(i) Outer Guide probe ( Shetah)**

Stainless Steel 304/306 Medical Grade ( probe)  
ABS Polymer Medical Grade ( Handle)  
Soft Tip – Silicon Sleeve Medical Grade ( Probe Tip)

**(D) Viewing Endoscope Materials:**

**(i) Rod Lense System :**

Outer Tubing : stainless Steel 304/306 Medical Grade  
Rod Lense optics : Quartz

**(ii) Digital Viewing Endoscope :**

Flexible Endoscope outer Sheath : TFE  
Rigid Endoscope outer Sheath : S.S. 316  
Optical window : Glass (Quartz)  
Endoscope Handle: Medical grade ABS Polymer

**(E) Delivery Devices :**

Injection Needle: Stainless Steel 304/306 Medical Grade  
RF Electrodes : Stainless Steel 304/306 Medical Grade  
Catheters; Polyurethane , PBEX, PVC  
RF electrode Insulation: TFE / FEP  
Hub Connector : Poly carbonate  
Monopolar / Bipolar Connection: Stainless Steel 304/306

**(F) Packaging:** Blister Tray & Tyvek Lid Package

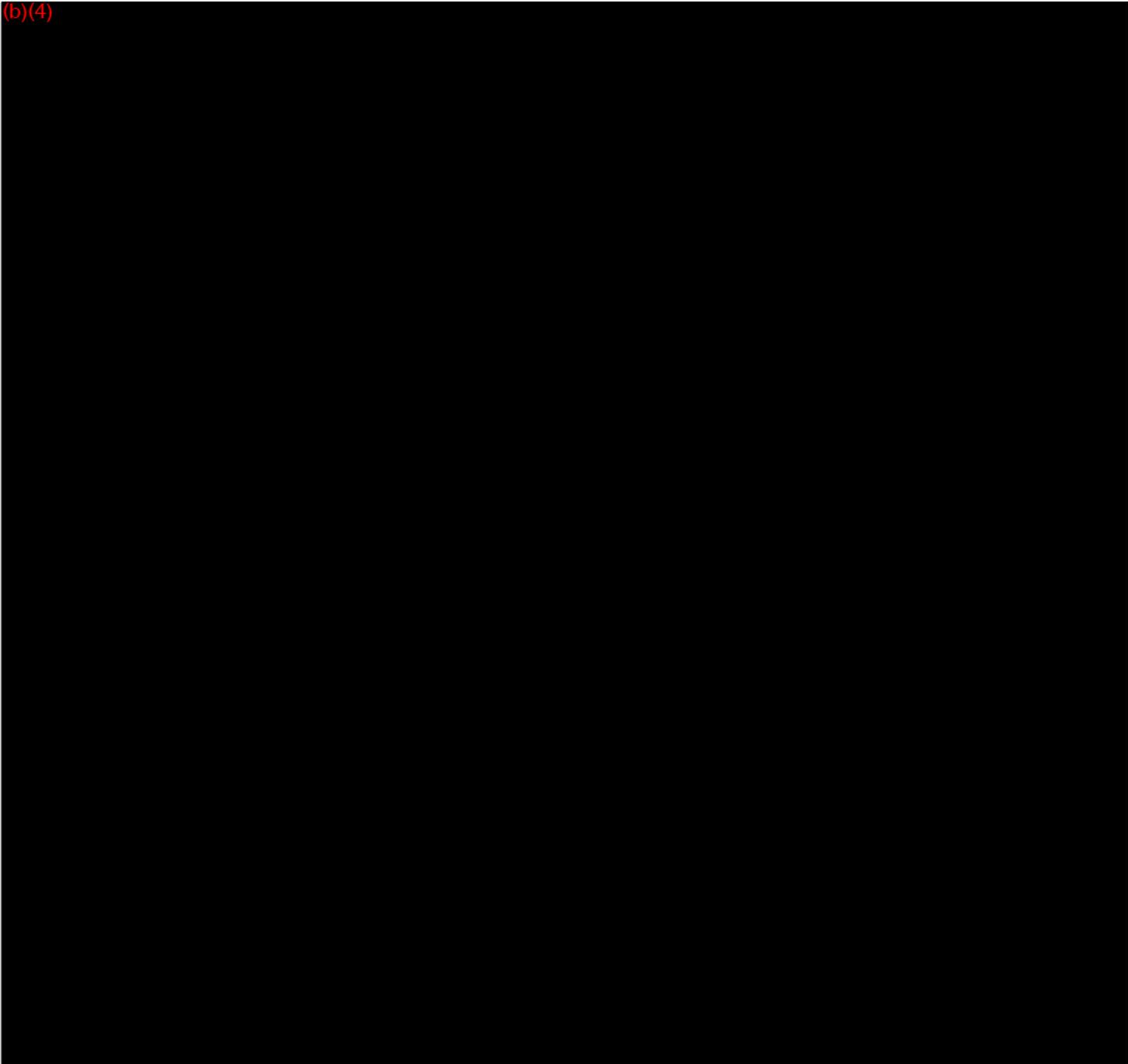
## **Material Biocompatibility**

### **NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification )**

The materials used for manufacturing and packaging of NeoScope™- Endoscopic Diagnostic & Treatment System ( modification) are identical to predicate device and are safe and biocompatible materials, that are widely used in the medical industry.

NeoScope™- Digital endoscope ( Rigid & Flexible) Devices are made from stainless Steel 304 /306 covered with TFE tubing and Medical Grade ABS molded handle. Neoscope - Endoscopic Diagnostic and Treatment System ( modification ) is identical in materials, manufacturing methods , assembly, packaging and sterilization as predicated device. The delivery devices , made from stainless steel(304 / 306) with medical grade ABS polymer handle and polycarbonate connectors. All of the materials have long established history of biocompatibility and use in medical devices. The packaging materials including tyvek lid and PETG blister tray are also identical as the predicate device. The packaging materials are not patient contact items and are not utilized in the medical procedures. The Video interface module and video display monitors are commercially available and are also non patient contact items.

(b)(4)



## Indications for Use

510(k) Number (if known):

Device Name: **NeoScope™ Endoscopic Diagnostic & Treatment System ( Modification )**

Indications For Use:

NeoScope™ Endoscopic Diagnostic & Treatment System ( Modification ) is intended for Cystoscopic, Hysteroscopic, Laparoscopic , Resectoscopic and Endoscopic treatment of Urological, Gynecological, Gastroenterological disorders and diseases of Prostate, Bladder, Urethra, Uterine cavity, Stomach, GI, Urinary tract and Reproductive organs using Biomaterials, Laser & RF devices, Tissue ablative and Augmenting agents, Microsurgical instruments and Endoscopic accessories.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of \_\_\_\_\_

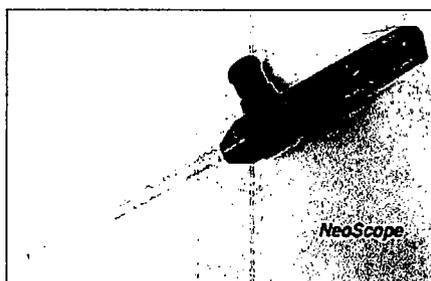
**Indications for Use:**

**NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification )**

NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification ) is intended for Cystoscopic, Hysteroscopic, Laparoscopic , Resectoscopic and Endoscopic treatment of Urological, Gynecological, Gastroenterological disorders and diseases of Prostate, Bladder, Urethra, Uterine cavity, Stomach, GI, Urinary tract and Reproductive organs using Biomaterials, Laser & RF devices, Tissue ablative and Augmenting agents, Microsurgical instruments and Endoscopic accessories.

**Product Labeling**

**NeoScope™- Digital Viewing Endoscope ( Rigid )**



**Model #** \_\_\_\_\_ **Qty:** 1 ea

**Endoscope Size: ( Dia )** \_\_\_\_\_ **Length :** \_\_\_\_\_  
( 5.0 / 7.0 / 10.0 mm ) ( 15.0 / 30.0 / 40.0 cm )

**Working Channel** \_\_\_\_\_  
( Yes / No )

**Date Of mfg:** \_\_\_\_\_ **Exp. Date :** \_\_\_\_\_

**Sterilization Method :** ETO Gas

**For Single use only**

Contents sterile unless package is damaged or open.

**Caution:** Federal (USA) law restricts this device to use by or on the order of a physician  
Please refer to Instructions for Use for additional information, & Guidelines

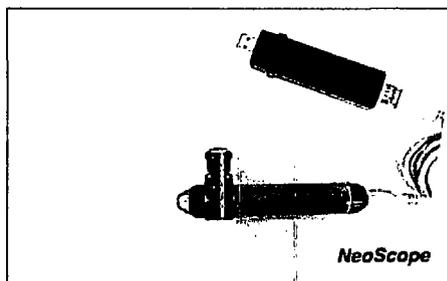
Lot # -----

P/N # ----- Rev ----

**Prosurg, Inc**  
2193 Trade Zone Blvd  
San Jose CA 95131  
Tel: 408 945 4040

### Product Labeling

#### NeoScope™- Digital Viewing Endoscope ( Flexible )



Model # \_\_\_\_\_

Qty: 1 ea

Endoscope Size: (Dia) \_\_\_\_\_ Length : \_\_\_\_\_  
(Dia 5.0 / 7.0 /10.0 mm) ( 30.0 / 45.0 / 70.0 cm)

Working Channel \_\_\_\_\_  
( Yes / No )

Date Of mfg: \_\_\_\_\_ Exp. Date : \_\_\_\_\_

Sterilization Method : ETO Gas

**For Single use only**

Contents sterile unless package is damaged or open.

**Caution:** Federal (USA) law restricts this device to use by or on the order of a physician  
Please refer to Instructions for Use for additional information, & Guidelines

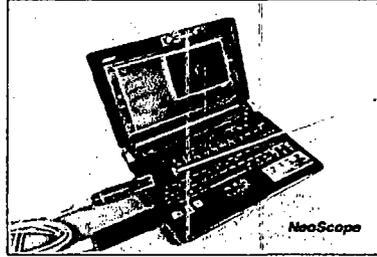
Lot # -----

P/N # ----- Rev ----

**Prosurg, Inc**  
2193 Trade Zone Blvd  
San Jose CA 95131  
Tel: 408 945 4040

**Product Labeling**

**NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification)**



**Model #** \_\_\_\_\_

**Qty:** 1 ea

**Endoscope Size: ( Dia )** \_\_\_\_\_  
( 5.0 / 7.0 / 10.0 mm)

**Length :** \_\_\_\_\_  
( 15.0 / 30.0 / 40.0 cm)

**Working Channel** \_\_\_\_\_  
( Yes / No )

**Date Of mfg:** \_\_\_\_\_

**Exp. Date :** \_\_\_\_\_

**Sterilization Method :** ETO Gas

**For Single use only**

Contents sterile unless package is damaged or open.

**Caution:** Federal (USA) law restricts this device to use by or on the order of a physician  
Please refer to Instructions for Use for additional information, & Guidelines

Lot # -----

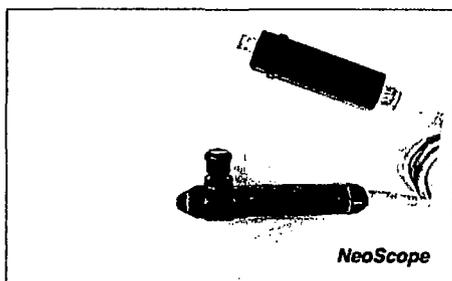
P/N # ----- Rev ----

**Prosurg, Inc**  
2193 Trade Zone Blvd  
San Jose CA 95131  
Tel: 408 945 4040

### Product Labeling

#### **NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification)**

#### **( Video Interface module & USB Connecting cable )**



**Model #** \_\_\_\_\_

**Qty:** 1 ea

**Video Module** \_\_\_\_\_  
( Window / Mac OS)

**USB Cable Length :** \_\_\_\_\_  
( 6.0 / 10.0 / 15.0 ft)

**Date Of mfg:** \_\_\_\_\_

**Exp. Date :** \_\_\_\_\_

**Sterilization Method :** ETO Gas

**For Single use only**

Contents sterile unless package is damaged or open.

**Caution:** Federal (USA) law restricts this device to use by or on the order of a physician  
Please refer to Instructions for Use for additional information, & Guidelines

Lot # -----

P/N # ----- Rev ----

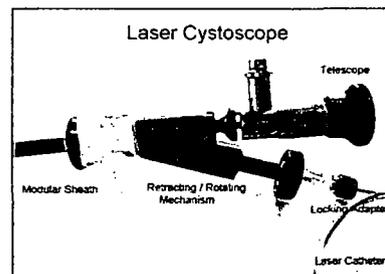
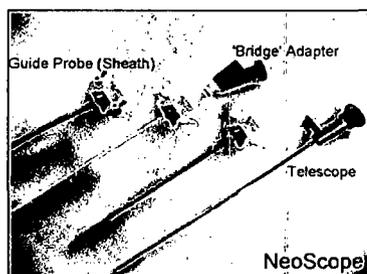
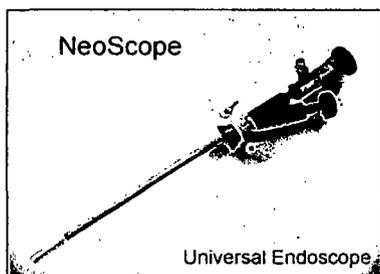
**Prosurg, Inc**  
2193 Trade Zone Blvd  
San Jose CA 95131  
Tel: 408 945 4040

## Instruction for Use

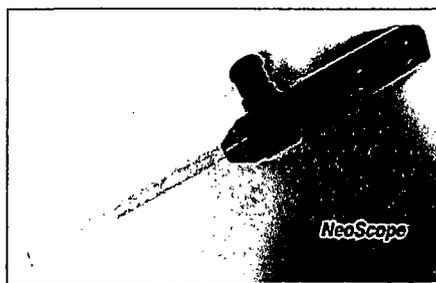
### NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification )

#### (1) Product Description:

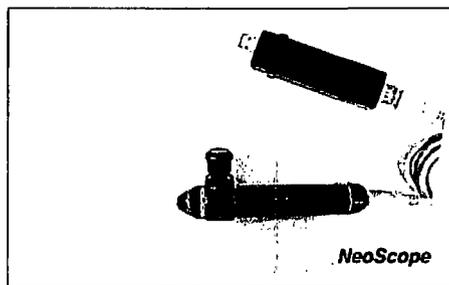
The NeoScope™- Endoscopic Diagnostic & Treatment System is a single use endoscopic diagnostic & surgical treatment device. The NeoScope, a modular endoscopic device is universally compatible with interchangeable components and various endoscopes to provide maximum utility and versatility to physician. The NeoScope endoscopic system consists of an Outer Guide probe (Sheath), connecting “Bridge” adapter, Delivery device and a viewing telescope / endoscope. The NeoScope outer guide probe is designed for continuous irrigation flow and is available in various sizes and configurations including Rigid, Semi-Rigid, Flexible, malleable design made from biocompatible polymer or metal for maximum patient safety and comfort.



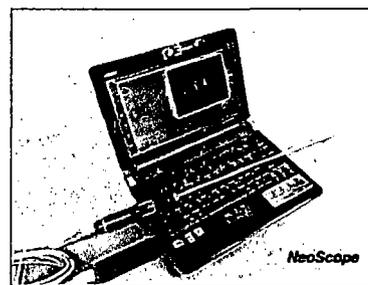
The modification to NeoScope™- Endoscopic System includes the use of a Digital viewing endoscope (Rigid / Flexible) with built-in LED light source and video module interface to a commercially available Laptop / Tablet computer / Smart phone or video Display Monitor. The Digital viewing endoscope incorporates a miniature CMOS (Complimentary Medical Oxide Semi- conductor) imaging sensor and LEDs ( Light Emitting Diodes) located at the distal tip, connecting wires along the length of the rigid or flexible tubular structure, USB connecting cord and a video module interface to a commercially available Laptop / Tablet computer / smart phone or video display monitor.



NeoScope- Digital endoscope



NeoScope w / Video Module



NeoScope w / Display Monitor

The product Configuration for NeoScope – Endoscopic Diagnostic & Treatment System are as follows

- (A) Diagnostic & Operative Cystoscope    (B) Diagnostic & Operative Laparoscope
- (C) Diagnostic & Operative Resectoscope    (D) Diagnostic & Operative Hysteroscope

## **(2) Indications For Use:**

NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification ) is intended for Cystoscopic, Hysteroscopic, Laparoscopic , Resectoscopic and Endoscopic treatment of Urological, Gynecological, Gastroenterological disorders and diseases of Prostate, Bladder, Urethra, Uterine cavity, Stomach, GI, Urinary tract and Reproductive organs using Biomaterials, Laser & RF devices, Tissue ablative and Augmenting agents, Microsurgical instruments and Endoscopic accessories.

## **Warnings:**

The NeoScope – Diagnostic & Treatment System ( modification) is intended for use by trained physicians only. The device should not be used until the physician is familiar with the instructions for use, assembly and care of the device. Equipment instruction manual should have been carefully studied and be available to the surgical / endoscopic team during the procedure. It is essential to follow the instructions contained in the equipment instruction manual pertaining to the devices used in the procedure, with particular attention given to the warnings and cautions. Care must be exercised during endoscopic procedure or the instrument may create perforation, infection or damage to the endoscope or deliver device. Care must be exercised during endoscopic insertion so as to avoid instrument damage or injury to the surrounding tissue. Possible injuries may include unintended tissue ablation beyond the zone of target tissue, compromised vasculature, injury or necrosis of underlying organs and surrounding tissue not targeted for the treatment. Endoscopic visualization or other imaging diagnosis must be performed during the procedure to verify that there is no potential damage to the other tissue structure or body organs. After the endoscopic procedure, the patient should be counseled for potential side effects and emergency instructions.

Contents supplied Sterile using an ethylene oxide (ETO) process. Do not use, if sterile barrier is damaged. If damage is found, please DO NOT USE. For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.

Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to Contamination of the another device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

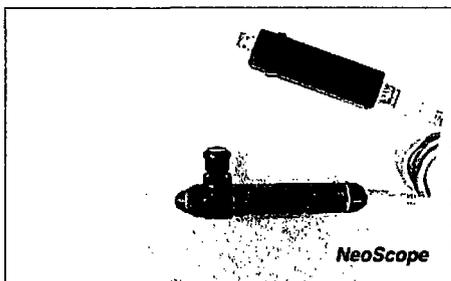
### **• Cautions:**

- Recommended for Single (one time) use only.
- Bending or kinking during or prior to placement could damage integrity of the endoscope and delivery devices.
- If resistance is encountered during advancement or withdrawal of the delivery device STOP. Do not continue without first determining the cause of the resistance and taking remedial action..

Federal (USA) law and governing law outside the USA restrict these devices to sale by or on the order of a physician.

### (3) Inspection and Assembly:

Use aseptic technique when removing the NeoScope™ – Endoscopic Diagnostic & Treatment System from package. Prior to use, carefully inspect the device for any visible signs of damage. DO NOT USE the device if it appears to be cracked, flawed, or otherwise damaged. DO NOT BEND OR MANIPULATE THE DEVICE.



Digital Endoscope & Video Module



Digital Endoscope, Video Module & Monitor

### (4) Diagnostic & Surgical Procedure:

4.1 Assemble NeoScope Endoscopic system using appropriate components for the desired diagnostic and treatment procedure. For Rod lense based endoscope insert the endoscope in to the system and connect to light source and video monitor.

For Digital Endoscope system, attach the connecting cord to the endoscope handle and video interface module. Insert the USB connector of video module into video monitoring device or computer. Start video capture or record by activating on/off switch mounted on the endoscope handle.

4.2, The NeoScope endoscopic system can be used for various endoscopic procedure for treatment of urological, uro-gynecological or gynecological disorders, using appropriate viewing telescope / endoscope.

4.3 The endoscopic tissue ablation procedure can be carried out under endoscopic visualization for laparoscopic, cystoscopic, hysteroscopic or other endoscopic procedure fro the treatment of various urological, uro-gynecological or gynecological disorders, using appropriate viewing telescope / endoscope.

4.4 Prepare the patient and operating work area. Select the appropriate diameter and length of the endoscope and delivery device fir the treatment procedure from the group consisting of injection needle for tissue ablation treatment or bulking agent, RF probe, Microwave device, Laser fiber optics catheter or Microsurgical instrument. Identify the appropriate delivery approach and treatment modality along with the imaging method to reach target tissue requiring treatment.

4.5 Insert the injection needle or other delivery device / probe into the target tissue using endoscopic visualization or ultrasound imaging probe. Attach pre-filled syringe to the injection needle or energy source connector to delivery probe. Make sure that the connection is secure.

4.6 Inject pre determined amount of he injectable in desired material form or apply the adequate amount of thermal energy under imaging guidance. Continue the treatment procedure for appropriate time to achieve desired tissue effect.

4.7 DO NOT ATTEMPT TO EXCEED TREATMENT PARAMETERS. Check for any signs of leakage of injection media from the target tissue. Aspirate or irrigate any excess treatment substance to minimize damage to the surrounding tissue, if necessary.

4.8 For Neoscope resectoscope use, insert delivery device with RF electrode in the proximity of the target tissue requiring resection, coagulation or vaporization. Connect RF energy ( Monopolar / Bipolar) supply to electrode and perform the procedure under endoscopic visualization.

4.9 For Laparoscopic and Hysteroscopic use, insert the delivery device under endoscopic visualization for tissue removal or tissue ablation procedure.

**5. STERILIZATION:**

The NeoScope™- Endoscopic Diagnostic & Treatment System are provided in sterile packaging and is intended for single use only. Do not use if the product if the sterility is compromised due to damaged package. We recommend that product be stored in a cool dry storage facility. The NeoScope™ accessories and packaging should be properly disposed of at the end of the procedure according to hospital/clinic policy. Do not attempt to re-sterilize

**6 GENERAL WARNING:**

The The NeoScope™- Endoscopic Diagnostic & Treatment System (Modification) is intended for use only by physicians. The user of the device should be thoroughly trained in its use and the applicable medical procedures. Use of these instruments and equipment should no be undertaken until the user has fully familiarized himself with the instructions for use, assembly and care. Equipment instruction manuals should have been carefully studied and be available to the surgical team during the procedure. It is essential to follow the instructions contained in instruction manual pertaining to devices used in the procedure, with particular attention given to the warnings and cautions. Care must be exercised during surgical procedure, or the instrument may potentially create perforation, infection, device damage or breakage. After the surgical procedure, the patient should be counseled for potential side effects, if any and emergency instructions.

**\*\*\*\*\* LIMITED WARRANTY\*\*\*\*\***

Prosurg, Inc warrants the NeoScope™- Endoscopic Diagnostic & Treatment System (modification) to be free from defects in material and workmanship for a period of 30 days from the day of shipment when properly installed, maintained, and used for its intended purpose. This warranty applies only to the original purchaser, and only so long as the equipment is used in the country to which Prosurg, Inc originally shipped it. This warranty is null and void if the user attempts to reuse, resterilize, or modify the device in any way. If after examination by Prosurg's Service Representative, any portion of the product is found to be defective within the period described above, and Prosurg, Inc is satisfied that the failure was due to defective materials and /or workmanship, Prosurg will, at its option, replace the defective product without charge.

THIS EXPRESS WARRANTY ABOVE IS THE SOLE WARRANTY OF OBLIGATION OF PROSURG, INC AND THE REDEMY PROVIDED ABOVE IS IN LIEU OF ANY AND ALL OTHER REDEMIES.THERE ARE NO OTHER AGREEMENTS, GUARANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. PROSURG, INC SHALL HAVE NO LIABILITY WHATSOEVER FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGE ARISING OUT OF ANY DEFECT, IMPROPER USE, OR UNAUTHORIZATION SERVICE OR REPAIR.

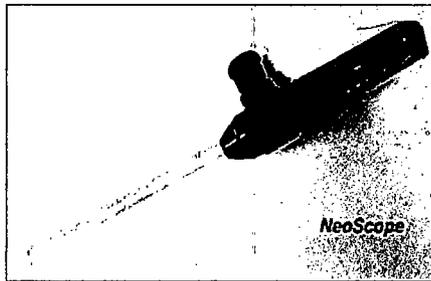
Prior to the return of the product, or any portion thereof, the Prosurg, Inc representative must be consulted. If return of the device/ instrument is deem necessary, a Returned Material Authorization number will be assigned. This number must be recorded on the outside of the shipping container and on the return packing list. Please contact:

Customer Service Dept.  
Prosurg, Inc  
[www.Prosurg.com](http://www.Prosurg.com)  
2193 Trade Zone Blvd.  
San Jose, CA 95131 U.S.A  
Tel.: (408) 945-4044

March 5, 2012

### **Substantially Equivalent Information**

#### **NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification )**



The NeoScope™- Endoscopic Diagnostic & Treatment System (Modification) is substantially equivalent to the predicated device NeoScope™- Endoscopic Diagnostic & Treatment System from ProSurg Inc, cleared by FDA under 510k application K# 042780 on Feb 3, 2005.. The only modification to the NeoScope Endoscopic System is to include the use of Digital endoscope device with CMOS sensor & LED module instead of a conventional “Rod lens” or “fiber optics” viewing endoscope and light source. The FDA regulatory clearance report, 510k application and product information details regarding predicated device is attached herewith for your review and consideration. Please review the comparison matrix outlining the Product specifications, Material compatibility and Indications for Use for the proposed device with predicated device. Please note that the proposed product is substantially equivalent to predicated devices in product design, materials, packaging and its intended use.

March 5, 2012

**Substantially Equivalent Information**

**NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification )**

<b>Company</b>	<b>Prosurg, Inc</b>	<b>Prosurg Inc</b>
<b>Product Name</b>	<b>NeoScope™- - Endoscopic Diagnostic &amp; Treatment System</b>	<b>NeoScope™- - Endoscopic Diagnostic &amp; Treatment System ( Modification)</b>
<b>510(k)</b>	<b>K042780</b>	<b>Applied for</b>
<b>Product Specifications:</b>		
<b>Material:</b>		
Endoscope Sheath	Stainless Steel / TFE	Stainless Steel / TFE
Endoscope distal End	Quartz Glass	Quartz Glass
<b>Dimensions:</b>		
Endoscope Diameter: ( mm )	1.0mm – 12 .0 mm	5.0mm , 7.0mm & 10.0mm
Endoscope Length ( cm )	10 cm -45 cm	15 cm – 40 cm
Viewing Angle ( degree)	0 , 12 & 30 degree	0 & 30 degree
<b>Recommended Usage Sterile / Non - Sterile</b>	Single Use Only Supplied Sterile	Single Use Only Supplied Sterile

March 5, 2012

**Substantially Equivalent Information.**

**NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification)**

Product Name	Company	510(k)	Indication for Use
<b>NeoScope™- - Endoscopic Diagnostic &amp; Treatment System</b>	<b>Prosurg, Inc</b>	<b>K042780</b>	NeoScope™- Endoscopic Diagnostic & Treatment System is intended for Cystoscopic, Hysteroscopic, Laparoscopic, Resectoscopic and Endoscopic treatment of Urological, Gynecological, Gastroenterological disorders and diseases of Prostate, Bladder, Urethra, Uterine cavity, Stomach, GI, Urinary tract and Reproductive organs using Biomaterials, Laser & RF devices, Tissue ablative and Augmenting agents, Microsurgical instruments and Endoscopic accessories.
<b>NeoScope™- - Endoscopic Diagnostic &amp; Treatment System ( Modification )</b>	<b>Prosurg, Inc</b>	<b>Applied For</b>	NeoScope™- Endoscopic Diagnostic & Treatment System (Modification ) is intended for Cystoscopic, Hysteroscopic, Laparoscopic , Resectoscopic and Endoscopic treatment of Urological, Gynecological, Gastroenterological disorders and diseases of Prostate, Bladder, Urethra, Uterine cavity, Stomach, GI, Urinary tract and Reproductive organs using Biomaterials, Laser & RF devices, Tissue ablative and Augmenting agents, Microsurgical instruments and Endoscopic accessories.

**Safety and Effectiveness of the Device  
(Ref: 807.7H, 907.92, and 807.93)**

**NeoScope™- Endoscopic Diagnostic & Treatment System ( Modification )**

We have conducted safety and effectiveness testing of *NeoScope™*- Endoscopic Diagnostic & Treatment System ( modification) and NeoScope Digital Endoscope ( Rigid & Flexible).

The modification to NeoScope™- Endoscopic System includes the use of a Digital viewing endoscope (Rigid / Flexible) with built-in LED light source and video module interface connected to a video display monitoring devices. The Digital viewing endoscope incorporates a miniature CMOS (Complimentary Medical Oxide Semi- conductor) imaging sensor and LEDs ( Light Emitting Diodes) located at the distal tip, connecting wires along the length of the rigid or flexible tubular structure and endoscope handle with USB interface. The Neoscope can be connected to a commercially available video monitor or tablet computer / mobile phone, using connecting cable. The proposed modification to NeoScope System using digital viewing endoscope can provide maximum utility to physician for endoscopic diagnostic and therapeutic applications of the internal body organs. Test data based on laboratory testing have demonstrated that the product meets the specifications, is safe and effective for its intended use.

NeoScope™- Endoscopic Diagnostic & Treatment System ( modification) and NeoScope Digital Endoscope ( Rigid & Flexible) are safe and effective during endoscopic viewing of various body organs and disorders, for diagnostic and treatment procedures.

**Product Shelf Life:**

The recommended Shelf life of the NeoScope™- Endoscopic Diagnostic & Treatment System ( modification) and NeoScope Digital Endoscope ( Rigid & Flexible) is one year. The product shelf life was determined as per Accelerated aging techniques, based on the assumptions that the chemical reactions involved in the deterioration of materials follow the Arrhenius reaction rate function. The sterilized products were subjected to environmental conditions & were tested to confirm product performance and packaging integrity specifications. The Shelf life report is attached herewith for your review and approval. The Real –Time aging test for 12 month will be initiated out upon completion of first manufacturing production lot.

**(14) Form FDA 3654 :**

The Form 3654 for relevant standards used in 510K application is submitted herewith for your review and approval. ( Please see attached)

Records Processed under Department of Health and Human Services, Food and Drug Administration  
 FOIA Request 2015-10055, Released by CDRH on 07/08/2016

**STANDARDS DATA REPORT FOR 510(k)s**  
 (To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

Please answer the following questions

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # \_\_\_\_\_

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....       
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....       
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....       
 If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER <b>14-228</b>	SECTION TITLE <b>Sterilization of Health care prod. Biological Evaluation of Med. Device Part 7</b>	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED \*  
**Ethylene oxide**

DESCRIPTION  
**ETO sterilization validation ANSI/AAMI/ISO 11135-1 2007**

JUSTIFICATION

SECTION NUMBER <b>14-76</b>	SECTION TITLE <b>Biological Evaluation of Med. Device Part 7</b>	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED \*  
**Ethylene oxide Residual**

DESCRIPTION  
**ETO Residual Gas Levels ANSI/AAMI/ISO 10993-7:2008**

JUSTIFICATION

SECTION NUMBER <b>2-87</b>	SECTION TITLE <b>Biological Evaluation of Medical Devices</b>	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED \*  
**Biocompatibility - ISO 10993-10-2002**

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
1350 Piccard Drive, Room 400  
Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service**

**Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850**

**FEB - 3 2005**

Mr. Ashvin Desai  
Manager, Regulatory Affairs  
Prosurg, Inc.  
2193 Trade Zone Blvd.  
SAN JOSE CA 95131

Re: K042780  
Trade/Device Name: NeoScope™ – Endoscopic Diagnostic & Treatment System  
Regulation Number: 21 CFR §876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: 78 FAJ  
Dated: December 30, 2004  
Received: January 18, 2005

Dear Mr. Desai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): 510k # K042780

DEVICE NAME: Neoscope- Endoscopic & Treatment System

INDICATIONS FOR USE:

Neoscope™ - Endoscopic Diagnostic and Treatment System is intended for cystoscopic, hysteroscopic laparoscopic, resectoscopic and endoscopic treatment of urological, gynecological, gastroenterological disorders and diseases of prostate, bladder, urethra, uterine cavity, stomach, GI, urinary tract and reproductive organs using biomaterials, laser & RF devices, tissue ablative and augmenting agents, microsurgical instrument and endoscopic accessories.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  
(Per 21 CFR 801.105)

OR

Over-The-Counter-Use  
(Optional Format 1-2)

David A. Ferguson  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K042780



MAR 31 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Terrence E. Sullivan  
Director, Regulatory Affairs  
ACMI Corporation  
136 Turnpike Road  
SOUTHBOROUGH MA 01772

Re: K060269  
Trade/Device Name: ACMI® DUR-Digital Ureterscope and Choledochoscope System  
Regulation Number: 21 CFR §876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Codes: FBN and FGB  
Dated: January 30, 2006  
Received: February 1, 2006

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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ACMI® DUR-Digital Ureteroscope and Choledochoscope System  
ACMI Corporation  
136 Turnpike Road  
Southborough, MA 01772

Traditional 510(k) Notification  
510(k) Summary  
January 30, 2006

*K 060269 Pg 2 of 3*

The DUR®-D System is also indicated for the examination of bile ducts, and using additional accessories, to perform various diagnostic and therapeutic procedures during cholecystectomy.

### **Product Description**

The ACMI® DUR®- Digital Ureteroscope and Choledochoscope (DUR®-D) is a flexible endoscope that incorporates CMOS (complimentary medical oxide semiconductor) sensor technology to generate an image. There is a miniature CMOS sensor located in the distal tip, wiring running through the endoscope shaft, a printed circuit board (PCB), a light-emitting diode (LED) light source located in the handle, and an electrical cord that connects the endoscope to the Camera Control Unit.

The DUR®-Digital Ureteroscope and Choledochoscope can be introduced either through the urethra into the bladder or through a percutaneous tract into the abdominal cavity or kidney. The DUR®- Digital Ureteroscope and Choledochoscope may also be used to manage biliary calculi in a choledochoscope indication. The DUR®-D System uses a Camera Control Unit (CCU) that contains printed circuits boards (PCBs), software, power supply and power cables to process and display the images transmitted by the camera.

### **Technological Characteristics and Substantial Equivalence**

The ACMI® DUR-Digital Ureteroscope and Choledochoscope (DUR®-D) System, utilizes features incorporated into the following legally marketed predicate devices:

The ACMI® DUR-Digital Ureteroscope and Choledochoscope (DUR®-D) System utilizes the same flexible endoscope technology design as those used in the predicate DUR®-8E device (K012925 and K023358).

The DUR®- Digital Ureteroscope and Choledochoscope is dimensionally similar to the predicate DUR®-8E, having the same working channel diameter and length, and utilizes the same materials in its construction as the predicate DUR®-8E.

The DUR®-Digital Ureteroscope and Choledochoscope incorporates the same basic video imaging technology located in the endoscope as the predicate ACMI® Invisio™ ICN System (K042225).

Like the predicate DUR®-8E, the ACMI® DUR®-Digital Ureteroscope and Choledochoscope (DUR®-D) System is indicated for use in therapeutic and diagnostic procedures in the entire intrarenal collecting system, and may also be used to manage biliary calculi.

**ACMI® DUR-Digital Ureteroscope and Choledochoscope System**  
ACMI Corporation  
136 Turnpike Road  
Southborough, MA 01772

**Traditional 510(k) Notification**  
**510(k) Summary**  
January 30, 2006

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During design verification, the performance of the DUR®-D was compared against the physical performance characteristics of the predicate DUR®-8E and the digital visualization characteristics of the predicate Invisio™ ICN. Testing demonstrated that the performance requirements were met, and that the DUR®-D exhibited comparable performance characteristics to both the predicate DUR®-8E and predicate Invisio™ ICN.

In summary, the ACMI® DUR-Digital Ureteroscope and Choledochoscope (DUR®-D) System is substantially equivalent to the predicate devices and presents no new questions of safety or efficacy.

ACMI® DUR-Digital Ureteroscope and Choledochoscope System  
ACMI Corporation  
136 Turnpike Road  
Southborough, MA 01772

MAR 31 2006

Traditional 510(k) Notification  
510(k) Summary  
January 30, 2006

510(k) Summary of Safety and Effectiveness  
ACMI Corporation  
ACMI® DUR-Digital Ureteroscope and Choledochoscope System

K060269  
Pg. 1 of 2

**General Information**

Manufacturer: ACMI Corporation  
136 Turnpike Rd.  
Southborough, MA 01772-2104

Contact Person: Terrence E. Sullivan  
Director, Regulatory Affairs  
Tel. #: 508-804-2739  
Fax #: 508-804-2624

Date Prepared: January 30, 2006

**Device Description**

Classification Name: Endoscope and accessories  
(21 CFR 876.1500), Class II  
Surgical camera and accessories  
(21 CFR 878.4160), Class I

Trade Name: ACMI® DUR-Digital Ureteroscope and  
Choledochoscope System (DUR®-D)

Generic/Common Name: Endoscope, Video Camera and accessories

**Predicate Devices**

ACMI® Invisio™ ICN K042225  
ACMI DUR®-8E K012925 and K023358

**Intended Uses**

The ACMI® DUR-Digital Ureteroscope and Choledochoscope (DUR®-D) System (which includes the DUR-Digital Invisio™ Flexible Ureteroscope and Choledochoscope and IDC Invisio™ Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

ACMI® DUR-Digital Ureteroscope and Choledochoscope System  
ACMI Corporation  
136 Turnpike Road  
Southborough, MA 01772

Traditional 510(k) Notification  
Statement of Intended Use  
January 30, 2006

**Device Name:** ACMI® DUR-Digital Ureteroscope and Choledochoscope System

**510(k) Number:** K 060269

**Indications for use:**

The ACMI® DUR-Digital Ureteroscope and Choledochoscope (DUR®-D) System (which includes the DUR-Digital Invisio™ Flexible Ureteroscope and Choledochoscope and IDC Invisio™ Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures.

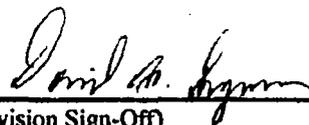
The DUR®-D System is also indicated for the examination of bile ducts, and using additional accessories, to perform various diagnostic and therapeutic procedures during cholecystectomy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:  OR Over-the-Counter Use:

(Per 21 CFR 801.109)



(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K060269