

K970107

**510(k) SUMMARY**

In accordance with the requirements of SMDA 1990 and 21 CFR 807.92 this 510(k) Summary of Safety and Effectiveness is submitted with the Premarket Submission.

Company Name: UROHEALTH Systems, Inc. NOV 18 1997  
3050 Redhill Ave.  
Costa Mesa, CA 92626

Contact Person: Ronald Bergeson  
Telephone Number: 714.708.7748, ext. 248

Device Name: Bronchoscope

Proprietary Device Name: Intubation Endoscope and  
Introducer Sheath

Classification Name: Bronchoscope (flexible or rigid) and  
accessories

Predicate Devices: SteBar Instr. Corp. Schroeder Oral/Nasal  
Stylette™  
Vision-Sciences EndoSheath®  
AMERICAN OPTICAL Flexible  
Brochoscope FBS-1  
Karl Storz Intubation Fiberscope

Device Description: UROHEALTH Intubation Endoscope Introducer  
Sheath is a device that consists a malleable or  
nonmalleable introducer sheath that houses a  
channel for insufflation of oxygen or fluid  
delivery, a deflecting mechanism for the distal  
tip, a channel for scope insertion, and a distal  
window. The reusable fiber optic imaging and  
illumination system consists of a focusing  
ocular lens, a distal objective lens, and a  
connection for a fiber optic light cable.

000048

- Intended Use:** The Intubation Endoscope and Introducer Sheath are used in the direct visualization in the trachea and lungs during fiberoptically assisted intubation and airway management.
- Performance Testing:** The Intubation Endoscope and Introducer Sheath will be tested to ensure integrity of the sterile barrier under normal usage conditions. All bonded joints will tested according to the appropriate ASTM procedure.
- Biocompatibility:** Biocompatibility testing will be conducted on both component level and finished devices (sterile, if applicable). This testing will include but is not limited to cytotoxicity, sensitization, and irritation. The device is considered body contact surface of mucosal membranes for a limited (less than 24 hours) contact duration. This testing is in accordance with EN 30993 for medical devices.
- Substantial Equivalence:** Based on the indications for use, technological characteristics, and safety and performance testing to be completed, the UROHEALTH Intubation Endoscope and Introducer Sheath will be shown to be safe and effective for its intended use.

000049



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 18 1997

Ronald Bergeson  
Corporate Director, Regulatory Affairs  
Imagyn (formerly UroHealth)  
5 Civic Plaza  
Suite 100  
Newport, CA 92660

Re: K970107  
Intubation Endoscope and Introducer Sheath  
Dated: October 7, 1997  
Received: October 8, 1997  
Regulatory class: II  
21 CFR 874.4680/Procode: 77 EOQ

Dear Mr. Bergeson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510 (k) Number (if known): K970107

Device Name: Intubation Endoscope and Introducer Sheath

Indications for Use:

The Intubation Endoscope is used for direct visualization in the trachea and lungs during fiberoptically assisted intubation and airway management.

(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 801.1091)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

*David C. Ferguson*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K970107



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 18 1997

Ronald Bergeson  
Corporate Director, Regulatory Affairs  
Imagyn (formerly UroHealth)  
5 Civic Plaza  
Suite 100  
Newport, CA 92660

Re: K970107  
Intubation Endoscope and Introducer Sheath  
Dated: October 7, 1997  
Received: October 8, 1997  
Regulatory class: II  
21 CFR 874.4680/Procode: 77 EOQ

Dear Mr. Bergeson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and at, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510 (k) Number (if known): K970107

Device Name: Intubation Endoscope and Introducer Sheath

Indications for Use:

The Intubation Endoscope is used for direct visualization in the trachea and lungs during fiberoptically assisted intubation and airway management.

(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 801.1091)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

David C. Segerson  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K970107



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Karen Baker

Subject: 510(k) Number K97010715<sup>+</sup>

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review 10/15/97 ✓
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO ✓
- Was this 510(k) reviewed by a Third Party?  YES  NO

This 510(k) contains:

- Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices n/a
- The indication for use form (required for originals received 1-1-96 and after)

*Handwritten:* UMM  
11-18-97

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class and tier: Additional Product Code(s) with panel (optional):

77 E00 874.4680 Class II

Review: [Signature] (Branch Chief) EWTB (Branch Code) 11/14/97 (Date)

Final Review: [Signature] (Division Director) 11/18 (Date)

*Handwritten:* 3



"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

**Document #** K970107

**Company Name:** Imagyn (formerly UroHealth)  
5 Civic Plaza  
Suite 100  
Newport, CA 92660  
(714) 720-8855  
FAX (714) 720-8809

**Contact Person:** Ronald Bergeson  
Corporate Director, Regulatory Affairs

**Device Name:** Intubation Endoscope and Introducer Sheath

**CLASSIFICATION NAME:** Bronchoscope and accessories  
**COMMON NAME:** Bronchoscope, rigid or flexible

**PRODUCT TO WHICH COMPARED:** (510(k) NUMBER IF KNOWN)

SteBar Instrument Corp, Schroeder Oral/Nasal Stylette  
Vision Sciences, EndoSheath - K961591  
American Optical, Flexible Bronchoscope FBS-1 - K811181  
Karl Storz, Intubation Fiberscope - K961178

**INTENDED USE STATEMENT:**

The Intubation Endoscope is intended to provide visualization in the trachea and lungs during fiberoptically assisted intubation and airway management.

✓

S

K970107/S1, page 2.

- |  | YES | NO |  |
|--|-----|----|--|
| 1. IS PRODUCT A DEVICE?  | X   |    | - IF NO STOP                           |
| 2. DEVICE SUBJECT TO 510(k)?   | X   |    | - IF NO STOP                           |
| 3. SAME INDICATION STATEMENT?  | X   |    | - IF YES GO<br>TO 5                    |
| 4. DO DIFFERENCES ALTER THE EFFECT<br>OR RAISE NEW ISSUES OF SAFETY OR<br>EFFECTIVENESS? |     |    | - IF YES STOP<br>- NE                  |
| 5. SAME TECHNOLOGICAL CHARACTERISTICS?   | X   |    | - IF YES<br>- GO TO 7                  |
| 6. COULD THE NEW CHARACTERISTICS AFFECT<br>SAFETY OR EFFECTIVENESS?                      |     |    | - IF YES GO<br>- TO 8                  |
| 7. DESCRIPTIVE CHARACTERISTICS PRECISE<br>ENOUGH?  | X   |    | - IF NO GO<br>- TO 10<br>- IF YES STOP |
| 8. NEW TYPES OF SAFETY OR EFFECTIVENESS<br>QUESTIONS?                                    |     |    | - IF YES STOP<br>- NE                  |
| 9. ACCEPTED SCIENTIFIC METHODS EXIST?  |     |    | - IF NO STOP<br>- NE                   |
| 10. PERFORMANCE DATA AVAILABLE?  |     |    | - IF NO<br>REQUEST DATA                |
| 11. DATA DEMONSTRATE EQUIVALENCE?  |     |    |  |

**Submission Provides**

Comparative Specifications:	yes
Comparative Lab Data:	no
Summary of Animal Testing:	no
Summary of Clinical Testing:	no
510(K) Statement:	no
510(K) Summary:	yes

6

K970107/S1, page 3.

## GENERAL INFORMATION SUMMARY

Life-Supporting or Life-Sustaining:	no
Is it an Implant?	no
Software Driven:	no
Level of Concern	
Certification	
Sterility: (single use sheath)	yes
Single Use:	
Disposable sheath	yes
Bronchoscope	no
Home or prescription use:	yes
Drug or Biologic product:	no
Device a kit:	no

Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the device design, materials, physical properties and toxicology profile if important.

## A. Device Description:

The Intubation Endoscope and Introducer Sheath system is comprised of two main components; a fiberoptic endoscope and an introducer sheath. The endoscope is inserted into the sheath and consists of a focusing ocular lens, a distal objective lens, optical and light fibers and a connection for a fiber optic light cable.

The introducer sheath consists of two channels, one for insufflation of oxygen and fluids, and one for scope insertion. The introducer sheath also has a mechanism to deflect the distal tip. The distal tip also contains a window through which the endoscope views the trachea and lungs. There are two models of introducer sheath; one that is malleable which contains a stainless steel wire to maintain the shape that is contoured by the physician for the patient's anatomy and, one that is nonmalleable which still contains a stainless steel wire but the wire is not malleable.

## B. Device Materials and Toxicity

The sponsor states that there are no patient contacting components in the fiberoptic scope.

K970107, page 4.

The patient contacting components in the introducer sheath are:

1. Bonding material - (b)(4)  
(b)(4)
2. Distal tip - (b)(4) Product
3. Pull tube - (b)(4)
4. Handle housing - (b)(4) Product
5. Female leuer - (b)(4) e
6. Distal window - (b)(4) e
7. Lumen body tubing - (b)(4) Product
8. Malleable wire - (b)(4) s
9. Scope tubing - (b)(4) i
10. Thumb lever - (b)(4) Product e

The sponsor states that biocompatibility testing will be conducted on both component level and finished devices (sterile, if applicable). This testing will include but is not limited to cytotoxicity, sensitization and irritation. This device is considered body contact surface of mucosal membranes for a limited contact duration (less than 24 hours). This testing is in accordance with EN 30993 for medical devices.

The sponsor states that the materials of construction of the distal tip and the sheath lumen are polyurethane.

#### C. Comparative Specifications

The sponsor includes a chart comparing the subject and predicate devices in terms of: tip deflection; deflection method; overall and working length; distal diameter; presence of an instrument or flushing channel; presence of a malleable sheath and biocompatibility. ✓

No description of optics or image quality is presented or compared. Overall diameter of the Insertion Sheath is not presented or compared.

#### D. Physical Properties and Performance Testing

Physical properties are described in terms of materials of the Introducer Sheath and the endoscope.

No testing of optical or image quality was presented in the original submission. This information was requested in an additional information letter. The firm responded with the following:

Technical and Optical Quality of the Flexible Endoscope: 8

K970107/S1, page 5.

Scope length  
Scope outer diameter:  
Intubation sheath diameter:

(b)(4) Product Specifications

Optical Performance: Objective Lens

Focal Length:  
Field of View  
Direction of View:

(b)(4) Product Specifications

Optical Performance: Illumination Fiber:

Ratio of luminous energy  
transmitted to energy  
delivered

(b)(4)

Optical Performance: Image Transmission:

Total number of  
fibers/pixels:  
Fibers/mm<sup>2</sup>  
Size of fiber core:  
Area of active fiber/mm<sup>2</sup>

(b)(4) Product Specifications

System:

Image Quality (Resolution): USAF Chart: Group 2, Element 6

No testing to demonstrate the microbial barrier properties of the sheath materials was presented in the original submission. The sponsor was asked to provide barrier test results. The sponsor provided test results of barrier testing performed in accordance with the guidance "Guidance for the Content of Premarket Notifications for Disposable, Sterile, Ear, Nose and Throat Endoscope Sheaths with Protective Barrier Claims". The results demonstrated no viral penetration in the 20 sheaths tested. The test appears to have been well controlled and executed.

#### E. Clinical Testing

No clinical testing is presented.

#### F. Sterilization

The sponsor states that both Gamma and ETO sterilization may be utilized. They further stated that validation will be accomplished per ANSI/AAMI/ISO guidelines for medical products. An overkill approach will be completed with a sterility assurance level (SA) of  $10^{-6}$ .

K970107/S1, page 6.

The sterile single use package will be a Tyvek to PET/LDPE laminated pouch sealed by conventional methods.

The user's information sheet did not contain complete instructions for cleaning the fiberscope between patient uses. The sponsor was asked to modify the labeling to include cleaning and low level disinfection as well as high level disinfection instructions. The response in the letter dated 10/8/97 was incomplete so a telephone call was placed. I discussed the need for cleaning instructions followed by low level disinfection followed by sterile water rinse to be performed after removal of the sheath, or high level disinfection if the user suspects contamination of the fiberscope. A fax was sent for my review and a hard copy is included.

#### G. Device Labeling

Proposed package labeling for the Malleable Introducer Sheath, (single unit and ten unit package); Nonmalleable Introducer Sheath (single unit and ten unit package); and Intubation Endoscope are included. The package labels (except Intubation Endoscope) include the statements that the devices are for single patient use, are sterile and provide the caution that the devices are restricted to sale by the order of a physician.

Also provided is sample instructions for use. The modified instructions include the requested information for reprocessing of the Intubation Endoscope, the reusable portion of the device.

#### H. 510(K) Summary or Statement

A 510(k) Summary is provided.

#### SUMMARY:

This device consists of a reusable fiberoptic endoscope called the Intubation Endoscope and a sterile, disposable Introducer Sheath (malleable and nonmalleable).

The Intubation Endoscope is inserted into the Introducer Sheath and consists of a focusing ocular lens, a distal objective lens, optical and light fibers and a connection for a fiber optic light cable. A video system may be connected to the optical coupler or direct visualization may be performed.

The Introducer Sheath consists of two channels, one for insufflation of oxygen and fluids, and one for scope insertion.

K970107/S1, page 7.

The Introducer Sheath also has a mechanism to deflect the distal tip. The distal tip contains a window through which the endoscope views the trachea and lungs. There are two models of Introducer Sheath; one that is malleable which contains a stainless steel wire to maintain the shape that is contoured by the physician for the patient's anatomy and, one that is nonmalleable which still contains a stainless steel wire but the wire is not malleable.

The sponsor adequately addressed the questions posed in the additional information letter dated April 8, 1997. This reviewer has no further questions regarding the Imagyn Intubation Endoscope and Introducer Sheath.



RECOMMENDATION:

The Imagyn Intubation Endoscope and Introducer Sheath are substantially equivalent to the cited predicate devices.

CFR# 874.4680  
Product Code 77-EOQ  
CLASS II

*Karen Baker*

-----  
Karen H. Baker RN, MSN

*11/6/97*

-----  
Date

*(11/1)*

*11/14*

*11*

Handwritten: Hanolon/A2



November 5, 1997

RECEIVED

Nov 6 10 11 AM '97

FDA/CDRH/OCE/DHC

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

Re: 510(k) Premarket Notification K970107  
Intubation Endoscope and Introducer Sheath  
Imagyn Medical Technologies, Inc.  
CLARIFICATION OF MATERIAL USED FOR STERILE BARRIER TEST

Dear Sir or Madam:

This letter is in response to a request made by Karen Baker in a phone conversation on Tuesday, November 4, 1997.

Imagyn confirms that the material used on the distal tip and all portions of the lumen involved in the sterile barrier testing is (b)(4) Product. That is the same material used to build current and future production units. These units will not be shipped until Imagyn receives a clearance letter from FDA.

Should you have any questions please contact me at (714) 720-8855.

Sincerely,

Ronald H. Bergeson  
Corporate Director, Regulatory Affairs  
Imagyn Medical Technologies, Inc.

Handwritten initials: SRS

5 Civic Plaza, Suite 100  
Newport Beach, CA 92660  
phone 714.668.5858

fax 714.668.5956  
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Handwritten number: 12



Karen Baker (HFZ-470)  
Food and Drug Administration  
Center for Devices and Radiological Health  
9200 Corporate Blvd.  
Rockville, Maryland 20850

Re: 510(k) Premarket Notification K970107  
Intubation Endoscope and Introducer Sheath  
Imagyn Medical Technologies, Inc.  
CLARIFICATION OF MATERIAL USED FOR STERILE BARRIER TEST  
DESK COPY

Dear Karen:

This letter confirms that the material used on the distal tip and all portions of the lumen involved in the sterile barrier testing was (b)(4) Product. That is the same material used to build current and future production units. These units will not be shipped until Imagyn receives a clearance letter from FDA

Three copies of this information have also been sent to the Document Mail Center.

Should you have any questions please contact me at (714) 720-8855.

Sincerely,

Ronald H. Bergeson  
Corporate Director, Regulatory Affairs  
Imagyn Medical Technologies, Inc.

13



November 5, 1997

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

Re: 510(k) Premarket Notification K970107  
Intubation Endoscope and Introducer Sheath  
Imagyn Medical Technologies, Inc.  
CLARIFICATION OF MATERIAL USED FOR STERILE BARRIER TEST

Dear Sir or Madam:

This letter is in response to a request made by Karen Baker in a phone conversation on Tuesday, November 4, 1997.

Imagyn confirms that the material used on the distal tip and all portions of the lumen involved in the sterile barrier testing is (b)(4) Product. That is the same material used to build current and future production units. These units will not be shipped until Imagyn receives a clearance letter from FDA.

Should you have any questions please contact me at (714) 720-8855.

Sincerely,

Ronald H. Bergeson  
Corporate Director, Regulatory Affairs  
Imagyn Medical Technologies, Inc.

5 Civic Plaza, Suite 100  
Newport Beach, CA 92660  
phone 714.668.5858  
fax 714.668.5856

Date: November 4, 1997  
To: The Record  
From: Karen Baker

Subject: K970107

I telephoned Mr. Ron Bergeron to clarify whether the material used for viral barrier testing is the same material will be used in the lumen of the sheath device. There are three materials listed that could be used for the lumen of the sheath and the material that was used in the viral challenge was not specified.

Mr. Bergeson responded that the polyurethane material to be used in the device is the same material that was tested in the viral barrier property test. See attached fax and hard copy to this effect.



Karen Baker, MSN, RN  
Nurse Consultant/ENTB

75

Handwritten: 11/4/14



**imagyn**

MEDICAL TECHNOLOGIES

November 3, 1997

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

Re: 510(k) Premarket Notification K970107  
Intubation Endoscope and Introducer Sheath  
Imagyn Medical Technologies, Inc.  
REVISED INSTRUCTIONS FOR USE

Dear Sir or Madam:

Thank you for notifying us of the need to modify the Instructions for Use (IFU) to include the statements about cleaning and disinfecting the scope after each use. These changes have been made and are included in the IFU attached.

Should you have any questions please contact me at (714) 720-8855.

Sincerely,

Ronald H. Bergeson  
Corporate Director, Regulatory Affairs  
Imagyn Medical Technologies, Inc.

FDA/CDRH/OCE/DIC

NOV 4 10 05 AM '97

RECEIVED

Handwritten: 16



November 3, 1997

Karen Baker (HFZ-470)  
Food and Drug Administration  
Center for Devices and Radiological Health  
9200 Corporate Blvd.  
Rockville, Maryland 20850

Re: 510(k) Premarket Notification K970107  
Intubation Endoscope and Introducer Sheath  
Imagyn Medical Technologies, Inc.  
REVISED INSTRUCTIONS FOR USE - DESK COPY

Dear Karen:

Thank you for notifying us of the need to modify the Instructions for Use (IFU) to include the statements about cleaning and disinfecting the scope after each use. These changes have been made and are included in the IFU attached.

Three copies have also been sent to the Document Mail Center.

Should you have any questions please contact me at (714) 720-8855.

Sincerely,

Ronald H. Bergeson  
Corporate Director, Regulatory Affairs  
Imagyn Medical Technologies, Inc.

17



DRAFT

**AeroView™**  
OPERATOR'S MANUAL

P/N 71461  
A00750-A  
October 1997

18

Before attempting to use AeroView in an actual patient care situation, operating personnel must become thoroughly familiar with the instructions in this manual.

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

If you have any questions on the use of AeroView, or need customer assistance, please contact your Imagyn Sales Representative or call Imagyn Medical Technologies Customer Service within the United States at: **(888) 876-4584**

---

## TABLE OF CONTENTS

<b>1.0</b>	<b>INTRODUCTION</b>	<b>4</b>
1.1	Intended Use	4
1.2	Overview	4
1.3	Description of the AeroView Scope System	4
<b>2.0</b>	<b>USING THE AEROVIEW SCOPE SYSTEM</b>	<b>6</b>
2.1	Preparation of the AeroView Scope	6
2.2	Preparation of the AeroView Sheath	6
2.3	Operating the AeroView Scope System	7
<b>3.0</b>	<b>MAINTENANCE</b>	<b>9</b>
3.1	Maintaining AeroView	9
4.2	Cleaning the AeroView Scope	9
<b>4.0</b>	<b>TROUBLESHOOTING GUIDE</b>	<b>10</b>
<b>5.0</b>	<b>GENERAL INFORMATION</b>	<b>11</b>
5.1	User/Owner Responsibility	11
5.2	Specifications	12
5.3	Warranty	12
<b>6.0</b>	<b>WARNINGS AND CAUTIONS</b>	<b>13</b>

30

## **1.0 INTRODUCTION**

### **1.1 Intended Use**

The AeroView Scope System is a fiberoptic visualization device that is used for fiberoptic oral or nasal intubation and fiberoptic airway endoscopy.

### **1.2 Overview**

AeroView offers an effective, safe, easy, and fast approach in patients who present difficult intubation problems with conventional techniques. In addition, AeroView permits evaluation of the patient's airway prior to, during, or after endotracheal tube placement.

Visualization of the airway provides the opportunity to evaluate the airway prior to tube placement, differentiate the cause of airway compromise, and allow precise placement of the endotracheal tube. Video endoscopy enhances visualization by displaying the image on a monitor. In addition, since AeroView is designed to work with Imagyn's videoendoscope system EndoView, you are guaranteed clear, accurate viewing during intubation.

AeroView is intended for use by anesthesiologists, nurse anesthetists, critical care physicians. It can be used in the operating room, intensive care unit, and emergency room.

### **1.3 Description of the AeroView Scope System**

The fiberoptic visualization device consists of two primary components: a flexible fiberoptic imaging bundle, the fiberscope a disposable introducer sheath

The flexible fiberscope is comprised of a coherent bundle of optical fibers which connect to the AeroView optical coupler.

## **AeroView Sheath**

The sheath is used to introduce and manipulate the fiberscope during use. The fiberscope is inserted into the sterile introducer sheath. The sheath is then placed within a sterile endotracheal tube. The sheath has been designed to prevent the fiberscope from coming in contact with bodily fluids. The AeroView sheath consists of the following parts:

### **Deflection Lever**

- the tip of the AeroView sheath may be deflected to aid in visualization and directing the endotracheal tube to its appropriate location
- depressing the deflection lever results in deflection of the sheath's tip; release of the lever returns the sheath to its neutral position

### **Flush Port**

- permits injection of sterile water to aid flushing of secretions or bodily fluids from the optics, instillation of local anesthetics, and/or delivery of oxygen

### **Illumination Connector**

- this connector is used to connect the AeroView fiberoptic light cable to the AeroView

### **Fiberscope Connector**

- This connector holds the AeroView fiberoptic scope securely in place during use

### **Endotracheal Tube Insertion Cuff**

- the AeroView sheath is inserted into a sterile endotracheal tube; the endotracheal tube adapter then fits into the sheath's cuff
- rotation of the cuff permits adjustment for varied endotracheal tube length, based on the physician's discretion

---

## **2.0 USING THE AEROVIEW SCOPE SYSTEM**

In addition to reading the following instructions for system set up and operation, also refer to the operator's manual(s) supplied with your light source, accessories, and other ancillary equipment. If using EndoView™, please refer to the EndoView Operator's Manual. The AeroView sheath is designed only for use with the AeroView flexible fiberoptic scope.

### **2.1. Preparation of the AeroView Scope**

1. Carefully remove the AeroView fiberscope from its protective case. Do not discard this case. It will be used for storing the AeroView fiberscope and light cable when not in use.
2. Insert the optical connector of the fiberscope into the optical coupler that is connected to the camera.
3. Insert the fiberoptic light cable connector into the output socket of the light source and turn the light source on.

### **2.3 Preparation of the AeroView Sheath**

The AeroView Sheath is supplied sterile. Use appropriate aseptic technique to maintain sterility of the device prior to use.

1. Using aseptic technique, remove the sheath from its package.
2. While depressing the deflection lever, make sure the tip of the sheath deflects smoothly and correctly.
3. Insert the AeroView fiberscope into the fiberscope connector located on the sheath's handle. Insert it until you reach a "stop" point.
4. Connect the fiberoptic light cable to the connector located on the sheath's handle, ensuring a secure connection.

23

---

## 2.3 Operating the AeroView Scope System

1. Insert the AeroView sheath into a sterile endotracheal tube such that the tip of the sheath extends slightly from the distal end of the endotracheal tube. Avoid insertion through the Murphy's eye as this will make visualization and removal of the fiberscope difficult. Turn the bottom of the insertion cuff to secure the endotracheal tube connector.

NOTE: A water soluble or local anesthetic lubricant may be applied to the distal one-third of the sheath to facilitate its insertion and removal from the endotracheal tube.

NOTE: Just prior to intubation, it may be beneficial to apply a few drops of a sterile anti-fog solution to the tip of the sheath to prevent fogging, thus providing better visualization.

2. Insert the AeroView sheath and endotracheal tube assembly into the patient's mouth using the standard intubation technique. It may be beneficial to use the midline approach. As the endotracheal tube is inserted, the airway is visualized on your video monitor.
3. The tip of the AeroView sheath may be deflected to aid in visualization and directing the endotracheal tube to its appropriate location. Depress the deflection lever to deflect the sheath's tip.
4. If local anesthetic is required during the intubation process it may be delivered through the injection port located on the AeroView sheath.
5. If visualization is difficult due to blood or mucus, injection of sterile water through the injection port will flush the optics.

6. After the endotracheal tube has been inserted, remove the sheath from the endotracheal tube by gently rotating the endotracheal tube insertion cuff and gently pulling the sheath out of the endotracheal tube.
7. Disconnect the fiberscope and fiberoptic light cable from their respective connectors on the sheath's handle.
8. Discard the sheath in an appropriate container.
9. Disconnect the light cable from the light source. If using a video system, disconnect the fiberscope from the video camera.
11. The AeroView fiberscope and light cable may then be placed in its protective case for the next use.

**NOTE:** If the fiberscope requires cleaning or disinfection, refer to Section 3 of this manual for proper instructions.

## **3.0 MAINTENANCE**

### **3.1 Maintaining AeroView**

**NOTE:** The AeroView fiberscope is a delicate instrument. Please take care during its handling. Take precautions not to bend and/or crush it.

It is recommended that after each use the AeroView Scope be cleaned and disinfected (please refer to Section 3.2 below for instructions). After cleaning and disinfection place the AeroView fiberscope and light cable inside the protective case. The AeroView sheath is a single patient use item and is to be discarded after use.

**NOTE:** After each use and whenever necessary, the optical surfaces of the coupler and should be wiped with a lint-free swab dampened with 70% isopropyl alcohol in order to keep the optics free from debris.

After each use the proximal end of the fiberscope should be wiped with a cloth or gauze pad dampened with 70% isopropyl alcohol.

The fiberoptic light cable may be cleaned with a cloth or gauze pad dampened with 70% isopropyl alcohol.

### **3.2 Cleaning the AeroView Scope**

The AeroView Scope should be cleaned and disinfected after each use. It is recommended that the scope be cleaned with a cloth or gauze pad and a proteinaceous enzymatic cleaning agent followed by low level disinfection, e.g., by wiping with a cloth or gauze pad dampened with 70% isopropyl alcohol. After each cleaning procedure the scope is to be thoroughly rinsed and dried before placing it in its protective case.

If there is patient contamination of the scope there should be high level disinfection or sterilization performed.

Sterilization of the fiberscope can be achieved by using a 2.4% glutaraldehyde solution, ethylene oxide (EtO) gas systems, or STERIS per the sterilant manufacturer's instructions.

27

## 4.0 TROUBLESHOOTING GUIDE

Situation	Action Taken
<p>Tip of AeroView sheath does not deflect</p>	<p>Depress deflection lever</p> <p>Obtain another sheath</p>
<p>Visualization difficult during coupler. intubation procedure</p>	<p>Adjust focus on optical</p> <p>Adjust brightness control on the light source.</p> <p>Ensure light cable connection on the illumination port located on the sheath is secure.</p> <p>Ensure light cable is securely connected to the light source.</p> <p>Ensure that all power cables are securely connected.</p> <p>Verify that the sheath and fiberscope assembly have not been inserted through the Murphy's eye of the endotracheal tube.</p> <p>Inject sterile water through the flush port of the sheath.</p>
<p>After the fiberscope has been inserted into sheath, one can view the sheath tip or orifice of the endotracheal tube .</p>	<p>Gently insert the fiberscope deeper into the sheath until the orifice is no longer in view.</p>

11 28

---

## 5.0 GENERAL INFORMATION

### 5.1 User/Owner Responsibility

This Imagyn equipment and the authorized accessories are designed to function as specified in the relevant Operator's Manual

only when operated and maintained in accordance with supplied manuals and instructions.

### 5.2 Specifications

AeroView sheath is designed only for use with the AeroView flexible fiberoptic scope. The AeroView flexible fiberoptic scope has the following performance characteristics:

- Focal Length            3 mm - 10 mm
- Field of View             $70^{\circ} \pm 5^{\circ}$
- Depth of Field            $0^{\circ} \pm 5^{\circ}$

### 5.3 Warranty

Imagyn warrants the AeroView fiberscope to be free from failures due to defects in material and workmanship, or malfunctions under normal use for a period of 90 days after purchase. During the warranty period, Imagyn will replace your fiberscope at no charge, with next-day delivery, if it fails to perform as specified.

If the fiberscope has been modified without Imagyn's written consent, or if the failure is the result of misuse, abuse, neglect, or improper installation or operation, Imagyn has no obligation to replace the fiberscope, and all warranties are null and void.

Should a malfunction occur within 90 days after purchase, the fiberscope must be returned to Imagyn or its authorized representative. Imagyn will replace the fiberscope at no cost to the customer. If, upon examination by authorized service personnel, it is determined that the malfunction is due to misuse or abuse, warranty provisions will not apply.

Before shipping a fiberscope for replacement, please call Imagyn Customer Service to obtain a Returned Materials Authorization Number (RMA). Please have the serial number of the fiberscope and a description of the problem ready before calling in order to help expedite the replacement. Prior to returning the fiberscope, it should be cleaned and disinfected. The fiberscope should be returned in original packaging material and shipping case to prevent shipping damage. The RGA number should be written on the box and returned to Imagyn.

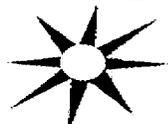
THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES EXPRESSED, IMPLIED, AND/OR STATUTORY INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS, AND/OR OF SUITABILITY FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS, OR LIABILITIES ON IMAGYN'S PART. IMAGYN NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER LIABILITIES IN CONNECTION WITH THE SALE OF SAID INSTRUMENTS AND EQUIPMENT. TO INSURE PROPER USE, HANDLING, AND CARE OF INSTRUMENTS AND EQUIPMENT, READ THIS OPERATOR'S MANUAL AND ANY OTHER LITERATURE WHICH MAY BE INCLUDED WITH THE PRODUCT AND/OR OTHERWISE AVAILABLE FROM THE COMPANY, AT NO CHARGE, UPON REQUEST

## 6.0 WARNINGS AND CAUTIONS

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

CAUTION: Do not steam sterilize the optical coupler. Exposure to temperatures greater than 140° may harm the unit and render it nonusable.

**AeroView™**  
*BEYOND THE SCOPE OF ANYTHING ELSE*



***imagyn***

*ANESTHESIA/CRITICAL CARE*

3050 Redhill Ave.  
Costa Mesa, CA 92626

32



---

### **3.0 MAINTENANCE**

#### **3.1 Maintaining AeroView**

**NOTE:** The AeroView fiberscope is a delicate instrument. Please take care during its handling. Take precautions not to bend and/or crush it.

It is recommended that after each use the AeroView Scope be cleaned and disinfected (please refer to Section 3.2 below for instructions). After cleaning and disinfection place the AeroView fiberscope and light cable inside the protective case. The AeroView sheath is a single patient use item and is to be discarded after use.

**NOTE:** After each use and whenever necessary, the optical surfaces of the coupler and should be wiped with a lint-free swab dampened with 70% isopropyl alcohol in order to keep the optics free from debris.

After each use the proximal end of the fiberscope should be wiped with a cloth or gauze pad dampened with 70% isopropyl alcohol.

The fiberoptic light cable may be cleaned with a cloth or gauze pad dampened with 70% isopropyl alcohol.

#### **3.2 Cleaning the AeroView Scope**

The AeroView Scope should be cleaned and disinfected after each use. It is recommended that the scope be cleaned with a cloth or gauze pad and a proteinaceous enzymatic cleaning agent followed by low level disinfection, e.g., by wiping with a cloth or gauze pad dampened with 70% isopropyl alcohol. After each cleaning procedure the scope is to be thoroughly rinsed and dried before placing it in its protective case.

---

If there is patient contamination of the scope there should be high level disinfection or sterilization performed.

Sterilization of the fiberscope can be achieved by using a 2.4% glutaraldehyde solution, ethylene oxide (ETO) gas systems, or STERIS per the sterilant manufacturer's instructions.

35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

October 08, 1997

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

UROHEALTH SYSTEMS INC.  
3050 REDHILL AVE.  
COSTA MESA, CA 92626  
ATTN: RONALD H. BERGESON

510(k) Number: K970107  
Product: INTUBATION  
ENDOSCOPE AND  
INTRODUCER  
SHEATH

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 (HFZ-401) 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. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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 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.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

36

K970107/57



October 7, 1997

Center for Devices and Radiological Health  
Document Mail Center (HFZ - 401)  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

RECEIVED  
OCT 8 9 35 AM '97  
FDA/CDRH/OCE/DWG

Re: Response to FDA Questions  
Intubation Endoscope And Introducer Sheath (Renamed AeroView™)  
K970107

Dear Sir or Madam:

This letter is in response to a letter dated April 8, 1997, received from the Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices, Office of Device Evaluation. That letter requested certain information for final review of the referenced premarket notification. The requested information is attached, with duplicate copies provided.

Please note that the name of the company and the name of the product have been changed. UROHEALTH Systems, Inc. has been changed to Imagyn Medical Technologies, Inc. effective October 1, 1997. The former name of the product (Intubation Endoscope and Introducer Sheath) has been changed to AeroView™, as shown in the attached instructions for Use.

Thank you for the opportunity to provide you with this information. If you have any questions please feel free to contact me at my new telephone number which is (714) 720-8855, or by Fax at (714) 720-8809. Please note my new address is 5 Civic Plaza, Suite 100, Newport Beach, CA 92660.

Sincerely,

Ronald H. Bergeson  
Corporate Director, Regulatory Affairs  
Imagyn Medical Technologies, Inc.

enclosures

cc: Karen Baker, HFZ-470

5 Civic Plaza, Suite 100  
Newport Beach, CA 92660  
phone 714.668.5858  
fax 714.668.5856

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

37

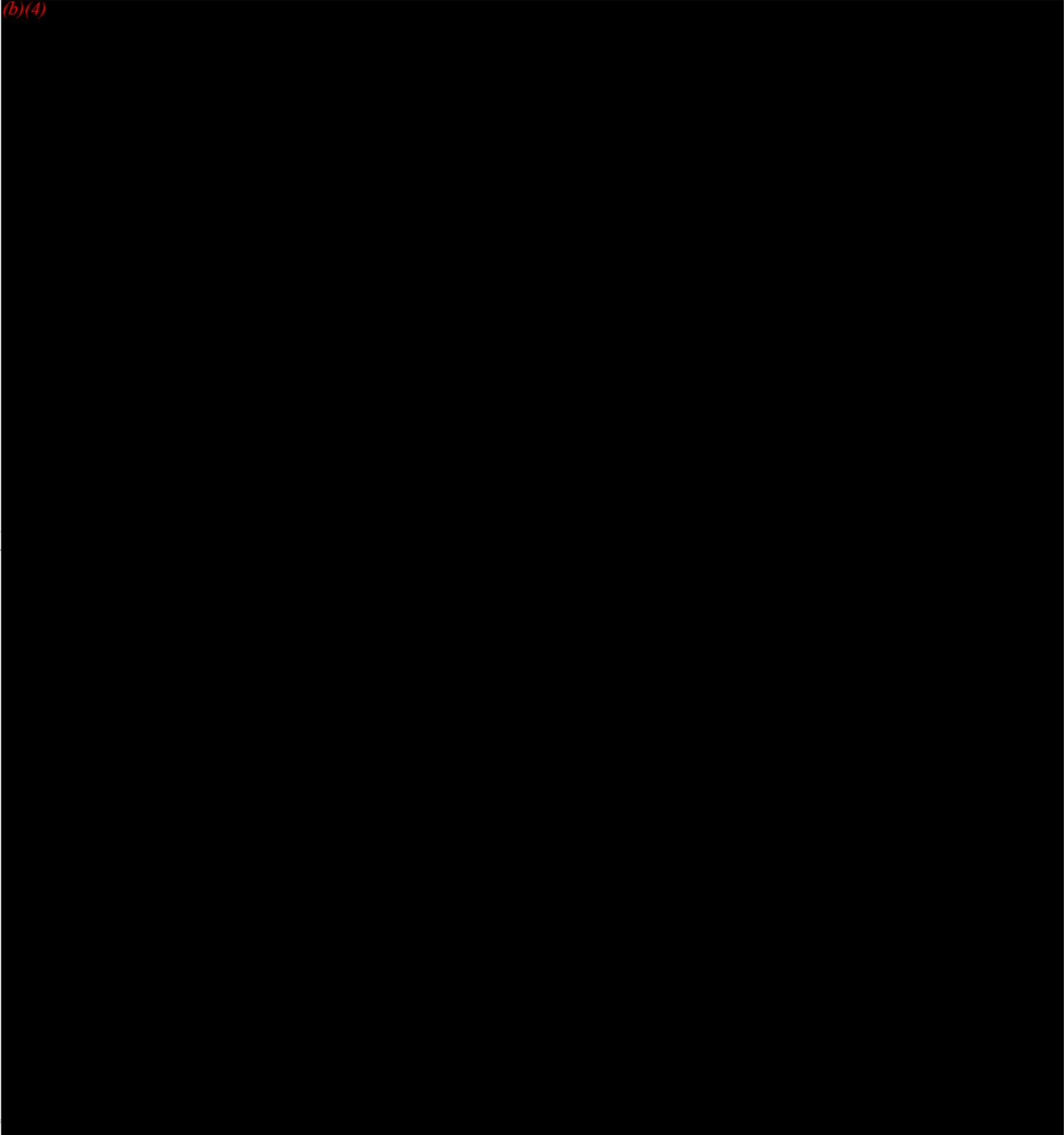
Intubation Endoscope And Introducer Sheath, K970107

October 7, 1997

Page 2

IMAGYN'S RESPONSES TO FDA QUESTIONS

(b)(4)



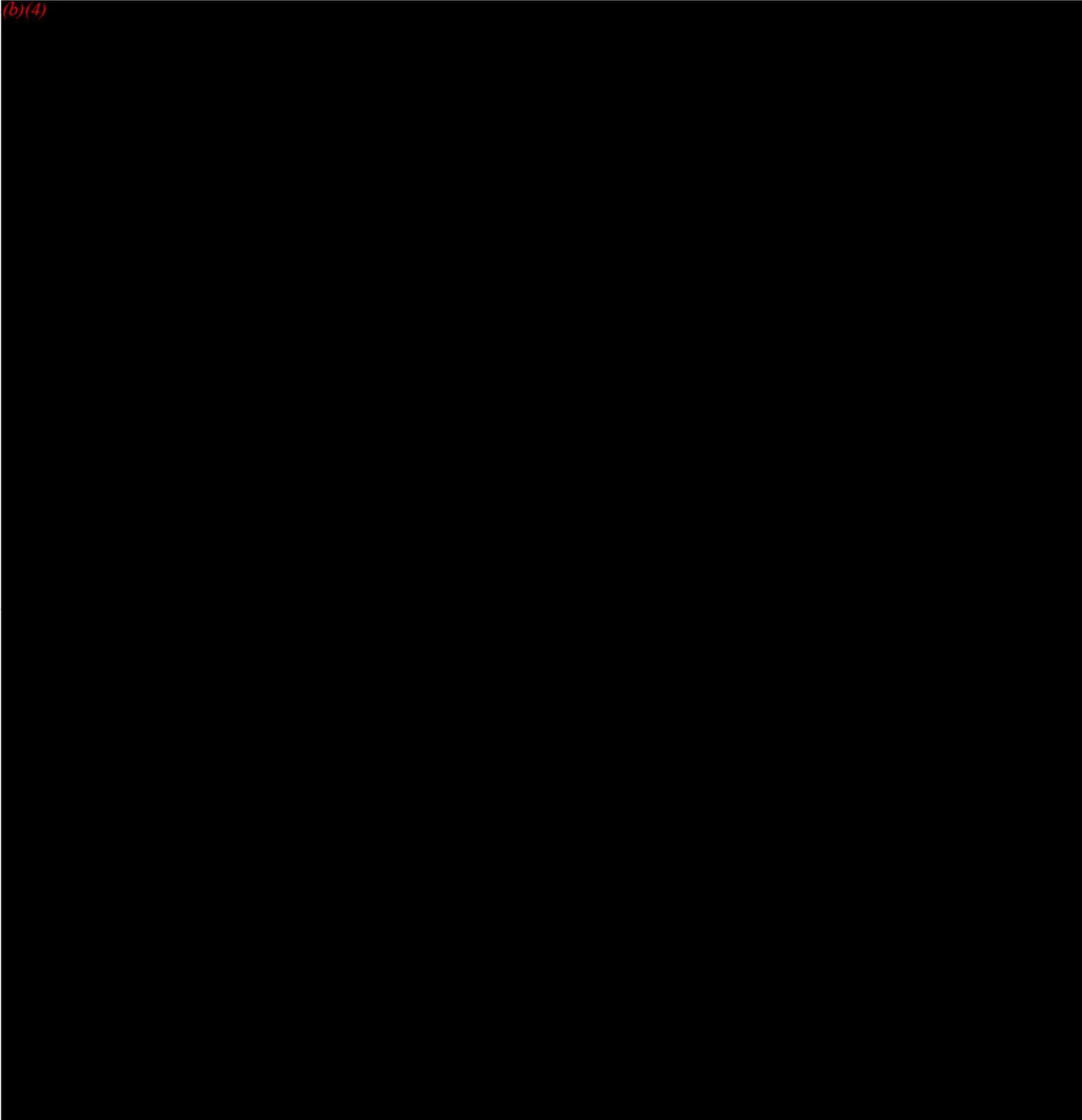
38

Intubation Endoscope And Introducer Sheath, K970107

October 7, 1997

Page 3

(b)(4)



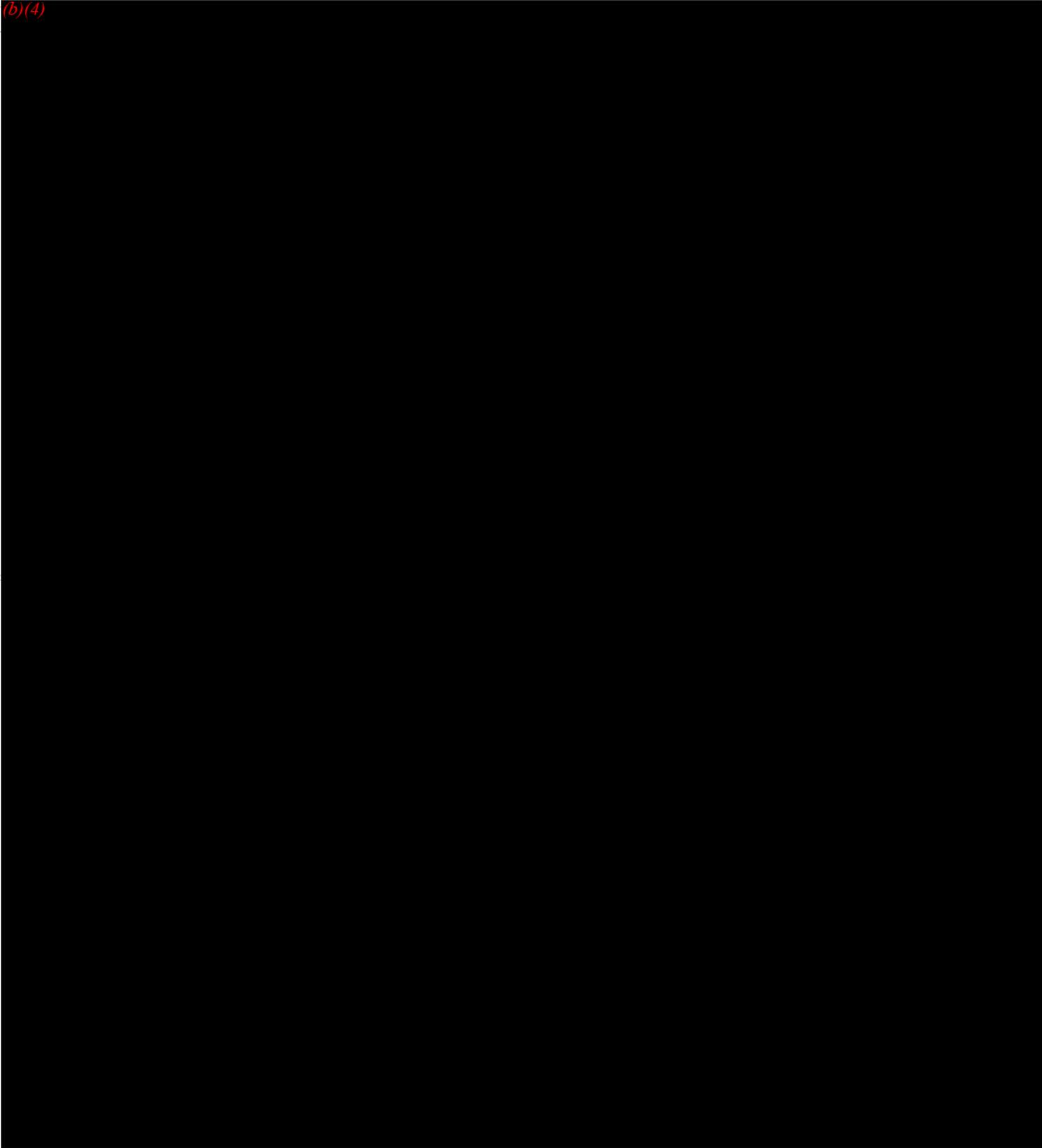
39

Intubation Endoscope And Introducer Sheath, K970107

October 7, 1997

Page 4

(b)(4)



h0

















DRAFT

**AeroView™**  
OPERATOR'S MANUAL

P/N 71461  
A00750-A  
October 1997

W8

Before attempting to use AeroView in an actual patient care situation, operating personnel must become thoroughly familiar with the instructions in this manual.

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

If you have any questions on the use of AeroView, or need customer assistance, please contact your Imagyn Sales Representative or call Imagyn Medical Technologies Customer Service within the United States at: **(888) 876-4584**

h9

---

## TABLE OF CONTENTS

<b>1.0</b>	<b>INTRODUCTION .....</b>	<b>4</b>
1.1	Intended Use .....	4
1.2	Overview .....	4
1.3	Description of the AeroView Scope System .....	4
<b>2.0</b>	<b>USING THE AEROVIEW SCOPE SYSTEM .....</b>	<b>6</b>
2.1	Preparation of the AeroView Scope .....	6
2.2	Preparation of the AeroView Sheath .....	6
2.3	Operating the AeroView Scope System .....	7
<b>3.0</b>	<b>MAINTENANCE .....</b>	<b>9</b>
3.1	Maintaining AeroView .....	9
4.2	Cleaning the AeroView Scope .....	9
<b>4.0</b>	<b>TROUBLESHOOTING GUIDE .....</b>	<b>10</b>
<b>5.0</b>	<b>GENERAL INFORMATION .....</b>	<b>11</b>
5.1	User/Owner Responsibility .....	11
5.2	Specifications .....	12
5.3	Warranty .....	12
<b>6.0</b>	<b>WARNINGS AND CAUTIONS .....</b>	<b>13</b>

50

---

## **1.0 INTRODUCTION**

### **1.1 Intended Use**

The AeroView Scope System is a fiberoptic visualization device that is used for fiberoptic oral or nasal intubation and fiberoptic airway endoscopy.

### **1.2 Overview**

AeroView offers an effective, safe, easy, and fast approach in patients who present difficult intubation problems with conventional techniques. In addition, AeroView permits evaluation of the patient's airway prior to, during, or after endotracheal tube placement.

Visualization of the airway provides the opportunity to evaluate the airway prior to tube placement, differentiate the cause of airway compromise, and allow precise placement of the endotracheal tube, Video endoscopy enhances visualization by displaying the image on a monitor. In addition, since AeroView is designed to work with Imagyn's videoendoscope system EndoView, you are guaranteed clear, accurate viewing during intubation.

AeroView is intended for use by anesthesiologists, nurse anesthetists, critical care physicians. It can be used in the operating room, intensive care unit, and emergency room.

### **1.3 Description of the AeroView Scope System**

The fiberoptic visualization device consists of two primary components: a flexible fiberoptic imaging bundle, the fiberscope a disposable introducer sheath

The flexible fiberscope is comprised of a coherent bundle of optical fibers which connect to the AeroView optical coupler.

## **AeroView Sheath**

The sheath is used to introduce and manipulate the fiberscope during use. The fiberscope is inserted into the sterile introducer sheath. The sheath is then placed within a sterile endotracheal tube. The sheath has been designed to prevent the fiberscope from coming in contact with bodily fluids. The AeroView sheath consists of the following parts:

### **Deflection Lever**

- the tip of the AeroView sheath may be deflected to aid in visualization and directing the endotracheal tube to its appropriate location
- depressing the deflection lever results in deflection of the sheath's tip; release of the lever returns the sheath to its neutral position

### **Flush Port**

- permits injection of sterile water to aid flushing of secretions or bodily fluids from the optics, instillation of local anesthetics, and/or delivery of oxygen

### **Illumination Connector**

- this connector is used to connect the AeroView fiberoptic light cable to the AeroView

### **Fiberscope Connector**

- This connector holds the AeroView fiberoptic scope securely in place during use

### **Endotracheal Tube Insertion Cuff**

- the AeroView sheath is inserted into a sterile endotracheal tube; the endotracheal tube adapter then fits into the sheath's cuff
- rotation of the cuff permits adjustment for varied endotracheal tube length, based on the physician's discretion

---

## 2.0 USING THE AEROVIEW SCOPE SYSTEM

In addition to reading the following instructions for system set up and operation, also refer to the operator's manual(s) supplied with your light source, accessories, and other ancillary equipment. If using EndoView™, please refer to the EndoView Operator's Manual.

The AeroView sheath is designed only for use with the AeroView flexible fiberoptic scope. ✓

### 2.1. Preparation of the AeroView Scope

1. Carefully remove the AeroView fiberscope from its protective case. Do not discard this case. It will be used for storing the AeroView fiberscope and light cable when not in use.
2. Insert the optical connector of the fiberscope into the optical coupler that is connected to the camera.
3. Insert the fiberoptic light cable connector into the output socket of the light source and turn the light source on.

### 2.3 Preparation of the AeroView Sheath

The AeroView Sheath is supplied sterile. Use appropriate aseptic technique to maintain sterility of the device prior to use.

1. Using aseptic technique, remove the sheath from its package.
2. While depressing the deflection lever, make sure the tip of the sheath deflects smoothly and correctly.
3. Insert the AeroView fiberscope into the fiberscope connector located on the sheath's handle. Insert it until you reach a "stop" point.
4. Connect the fiberoptic light cable to the connector located on the sheath's handle, ensuring a secure connection.

53

---

## 2.3 Operating the AeroView Scope System

1. Insert the AeroView sheath into a sterile endotracheal tube such that the tip of the sheath extends slightly from the distal end of the endotracheal tube. Avoid insertion through the Murphy's eye as this will make visualization and removal of the fiberoptic difficult. Turn the bottom of the insertion cuff to secure the endotracheal tube connector.

NOTE: A water soluble or local anesthetic lubricant may be applied to the distal one-third of the sheath to facilitate its insertion and removal from the endotracheal tube.

NOTE: Just prior to intubation, it may be beneficial to apply a few drops of a sterile anti-fog solution to the tip of the sheath to prevent fogging, thus providing better visualization.

2. Insert the AeroView sheath and endotracheal tube assembly into the patient's mouth using the standard intubation technique. It may be beneficial to use the midline approach. As the endotracheal tube is inserted, the airway is visualized on your video monitor.
3. The tip of the AeroView sheath may be deflected to aid in visualization and directing the endotracheal tube to its appropriate location. Depress the deflection lever to deflect the sheath's tip.
4. If local anesthetic is required during the intubation process it may be delivered through the injection port located on the AeroView sheath.
5. If visualization is difficult due to blood or mucus, injection of sterile water through the injection port will flush the optics.
6. After the endotracheal tube has been inserted, remove the sheath from the endotracheal tube by gently rotating the

SH

endotracheal tube insertion cuff and gently pulling the sheath out of the endotracheal tube.

7. Disconnect the fiberscope and fiberoptic light cable from their respective connectors on the sheath's handle.
8. Discard the sheath in an appropriate container.
9. Disconnect the light cable from the light source. If using a video system, disconnect the fiberscope from the video camera.
11. The AeroView fiberscope and light cable may then be placed in its protective case for the next use.

NOTE: If the fiberscope requires cleaning or disinfection, refer to Section 3 of this manual for proper instructions.

---

### **3.0 MAINTENANCE**

#### **3.1 Maintaining AeroView**

NOTE: The AeroView fiberscope is a delicate instrument. Please take care during its handling. Take precautions not to bend and/or crush it.

After use, place the AeroView fiberscope and light cable inside the protective case if the fiberscope does not require cleaning or disinfection. If it does, please refer to Section 3.2 below. The AeroView sheath is a single patient use item and is to be discarded after use.

NOTE: After each use and whenever necessary, the optical surfaces of the coupler be wiped with a lint-free swab dampened with 70% isopropyl alcohol in order to keep the optics free from debri.

The fiberoptic light cable may be cleaned with a cloth or gauze pad dampened with 70% isopropyl alcohol.

#### **3.2 Cleaning the AeroView Scope**

If the AeroView Scope requires cleaning or disinfection, it is recommended that the scope be cleaned with a cloth or gauze pad dampened with 70% isopropyl alcohol. It can then be disinfected using standard institutional guidelines for non-sterile instruments and equipment. After each cleaning procedure the scope is to be thoroughly rinsed and dried before placing it in its protective case.

Sterilization of the fiberscope can be achieved by using a 2.4% gluteraldehyde solution, ethylene oxide (ETO) gas systems, or STERIS per sterilant manufacturer's instructions.

## 4.0 TROUBLESHOOTING GUIDE

Situation	Action Taken
<p>Tip of AeroView sheath does not deflect</p>	<p>Depress deflection lever</p> <p>Obtain another sheath</p>
<p>Visualization difficult during intubation procedure</p>	<p>Adjust focus on optical coupler.</p> <p>Adjust brightness control on the light source.</p> <p>Ensure light cable connection on the illumination port located on the sheath is secure.</p> <p>Ensure light cable is securely connected to the light source.</p> <p>Ensure that all power cables are securely connected.</p> <p>Verify that the sheath and fiberscope assembly have not been inserted through the Murphy's eye of the endotracheal tube.</p> <p>Inject sterile water through the flush port of the sheath.</p>
<p>After the fiberscope has been inserted into sheath, one can view the sheath tip or orifice of the endotracheal tube</p>	<p>Gently insert the fiberscope deeper into the sheath until the orifice is no longer in view.</p>

57

---

## 5.0 GENERAL INFORMATION

### 5.1 User/Owner Responsibility

This Imagyn equipment and the authorized accessories are designed to function as specified in the relevant Operator's Manual only when operated and maintained in accordance with supplied manuals and instructions.

### 5.2 Specifications

AeroView sheath is designed only for use with the AeroView flexible fiberoptic scope. The AeroView flexible fiberoptic scope has the following performance characteristics:

- Focal Length            3 mm - 10 mm
- Field of View             $70^{\circ} \pm 5^{\circ}$
- Depth of Field            $0^{\circ} \pm 5^{\circ}$

### 5.3 Warranty

Imagyn warrants the AeroView fiberscope to be free from failures due to defects in material and workmanship, or malfunctions under normal use for a period of 90 days after purchase. During the warranty period, Imagyn will replace your fiberscope at no charge, with next-day delivery, if it fails to perform as specified.

If the fiberscope has been modified without Imagyn's written consent, or if the failure is the result of misuse, abuse, neglect, or improper installation or operation, Imagyn has no obligation to replace the fiberscope, and all warranties are null and void.

Should a malfunction occur within 90 days after purchase, the fiberscope must be returned to Imagyn or its authorized representative. Imagyn will replace the fiberscope at no cost to the customer. If, upon examination by authorized service personnel, it is determined that the malfunction is due to misuse or abuse, warranty provisions will not apply.

Before shipping a fiberscope for replacement, please call Imagyn Customer Service to obtain a Returned Materials Authorization Number (RMA). Please have the serial number of the fiberscope and a description of the problem ready before calling in order to help expedite the replacement. Prior to returning the fiberscope, it should be cleaned and disinfected. The fiberscope should be returned in original packaging material and shipping case to prevent shipping damage. The RGA number should be written on the box and returned to Imagyn.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES EXPRESSED, IMPLIED, AND/OR STATUTORY INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS, AND/OR OF SUITABILITY FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS, OR LIABILITIES ON IMAGYN'S PART. IMAGYN NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER LIABILITIES IN CONNECTION WITH THE SALE OF SAID INSTRUMENTS AND EQUIPMENT. TO INSURE PROPER USE, HANDLING, AND CARE OF INSTRUMENTS AND EQUIPMENT, READ THIS OPERATOR'S MANUAL AND ANY OTHER LITERATURE WHICH MAY BE INCLUDED WITH THE PRODUCT AND/OR OTHERWISE AVAILABLE FROM THE COMPANY, AT NO CHARGE, UPON REQUEST

S9

## 6.0 WARNINGS AND CAUTIONS

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

CAUTION: Do not steam sterilize the optical coupler. Exposure to temperatures greater than 140° may harm the unit and render it nonusable.

60

**AeroView™**

*BEYOND THE SCOPE OF ANYTHING ELSE*



***Imagyn***

*ANESTHESIA/CRITICAL CARE*

3050 Redhill Ave.

Costa Mesa, CA 92626

61

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

September 05, 1997

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

UROHEALTH SYSTEMS INC.  
3050 REDHILL AVE.  
COSTA MESA, CA 92626  
ATTN: RONALD H. BERGESON

510(k) Number: K970107  
Product: INTUBATION  
ENDOSCOPE AND  
INTRODUCER  
SHEATH

Extended Until: 08-NOV-97

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

62



September 4, 1997

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

Re: 510(k) Premarket Notification (K970107)  
Request for Extension  
INTUBATION ENDOSCOPE AND INTRODUCER SHEATH

RECEIVED  
5 SEP 97 10 11  
FDA/CDRH/OCE/DWG

Dear Sir or Madam:

This letter is in response to FDA's letter dated April 8, 1997 requesting additional information for technical review. FDA's letter requested the information be provided within 30 days.

UROHEALTH had asked for an extension until September 8, 1997. However, and as we discussed, the laboratory had difficulties performing this test due to the small size of the lumen. In the past such tests have been performed on lumens with a larger diameter, however our lumen size makes it difficult to get liquids in to verify the barrier integrity. Therefore we will not be able to provide the requested information within that time frame. UROHEALTH is working with this laboratory and an alternate to evaluate this product, and therefore we request an extension for our response until November 8, 1997.

If you have any questions please contact me at (714) 720-8855, or by Fax at (714) 720-8809. Please note that these are new numbers as well as my address which is 5 Civic Plaza, Suite 100, Newport Beach, CA 92660.

Sincerely,

  
Ronald H. Bergeson  
Corporate Director, Regulatory Affairs  
UROHEALTH Systems, Inc.

SK-6

63

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

July 16, 1997

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

UROHEALTH SYSTEMS INC.  
3050 REDHILL AVE.  
COSTA MESA, CA 92626  
ATTN: RONALD H. BERGESON

510(k) Number: K970107  
Product: INTUBATION  
ENDOSCOPE AND  
INTRODUCER  
SHEATH

Extended Until: 08-SEP-97

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

6h



July 10, 1997

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

FDA/CDRH/ODE/DMC

15 JUL 97 13 52

RECEIVED

Re: 510(k) Premarket Notification (K970107)  
Request for Extension  
INTUBATION ENDOSCOPE AND INTRODUCER SHEATH

Dear Sir or Madam:

This letter is in response to FDA's letter dated April 8, 1997 requesting additional information for technical review. FDA's letter requested the information be provided within 30 days.

UROHEALTH had originally asked for an extension until July 8, 1997. However, we will have been unable to locate a test house to perform the sterile barrier testing, and therefore are not be able to provide the requested information within that time frame. UROHEALTH is in the final stage of evaluating an alternate test, and therefore we request an extension for our response until September 8, 1997. I believe the testing and our response will be provided much sooner than that date.

If you have any questions please contact me at (714) 708-7748, extension 248.

Sincerely,

Ronald H. Bergeson  
Corporate Director, Regulatory Affairs  
UROHEALTH Systems, Inc.

SK-36  
LS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

May 08, 1997

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

UROHEALTH SYSTEMS INC.  
3050 REDHILL AVE.  
COSTA MESA, CA 92626  
ATTN: RONALD H. BERGESON

510(k) Number: K970107  
Product: INTUBATION  
ENDOSCOPE AND  
INTRODUCER  
SHEATH

Extended Until: 08-JUL-97

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

66



# UROHEALTH

RECEIVED

5 MAY 97 10 23

FDA/CDRH/ODE/DMC

May 2, 1997

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

Re: 510(k) Premarket Notification (K970107)  
Request for Extension  
INTUBATION ENDOSCOPE AND INTRODUCER SHEATH

Dear Sir or Madam:

This letter is in response to FDA's letter dated April 8, 1997 requesting additional information for technical review. FDA's letter requested the information be provided within 30 days.

However, we will not be able to provide the requested information within that time frame. UROHEALTH therefore requests an extension until July 8, 1997.

If you have any questions please contact me at (714) 708-7748, extension 248.

Sincerely,

Ronald H. Bergeson  
Corporate Director, Regulatory Affairs  
UROHEALTH Systems, Inc.

SK=21

67

K970107

**510(k) SUMMARY**

In accordance with the requirements of SMDA 1990 and 21 CFR 807.92 this 510(k) Summary of Safety and Effectiveness is submitted with the Premarket Submission.

Company Name: UROHEALTH Systems, Inc.  
3050 Redhill Ave.  
Costa Mesa, CA 92626

Contact Person: Ronald Bergeson  
Telephone Number: 714.708.7748, ext. 248

Device Name: Bronchoscope

Proprietary Device Name: Intubation Endoscope and  
Introducer Sheath

Classification Name: Bronchoscope (flexible or rigid) and  
accessories

Predicate Devices: SteBar Instr. Corp. Schroeder Oral/Nasal  
Stylette™

Vision-Sciences EndoSheath®

AMERICAN OPTICAL Flexible  
Brochoscope FBS-1

Karl Storz Intubation Fiberscope

Device Description: UROHEALTH Intubation Endoscope Introducer  
Sheath is a device that consists a malleable or  
nonmalleable introducer sheath that houses a  
channel for insufflation of oxygen or fluid  
delivery, a deflecting mechanism for the distal  
tip, a channel for scope insertion, and a distal  
window. The reusable fiber optic imaging and  
illumination system consists of a focusing  
ocular lens, a distal objective lens, and a  
connection for a fiber optic light cable.

68

000048

**Intended Use:** The Intubation Endoscope and Introducer Sheath are used in the direct visualization in the trachea and lungs during fiberoptically assisted intubation and airway management.

**Performance Testing:** The Intubation Endoscope and Introducer Sheath will be tested to ensure integrity of the sterile barrier under normal usage conditions. All bonded joints will be tested according to the appropriate ASTM procedure.

**Biocompatibility:** Biocompatibility testing will be conducted on both component level and finished devices (sterile, if applicable). This testing will include but is not limited to cytotoxicity, sensitization, and irritation. The device is considered body contact surface of mucosal membranes for a limited (less than 24 hours) contact duration. This testing is in accordance with EN 30993 for medical devices.

**Substantial Equivalence:** Based on the indications for use, technological characteristics, and safety and performance testing to be completed, the UROHEALTH Intubation Endoscope and Introducer Sheath will be shown to be safe and effective for its intended use.

69

K970107

510 (k) Number (if known): K970107

Device Name: Intubation Endoscope and Introducer Sheath

Indications for Use:

The Intubation Endoscope is used for direct visualization in the trachea and lungs during fiberoptically assisted intubation and airway management.

(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 801.1091)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

70

DIVISION OF CARDIOVASCULAR, RESPIRATORY AND NEUROLOGICAL DEVICES  
 DOCUMENT# K970107/S001 AN/ADDG /DCRND POS S  
 APPLICANT UROHEALTH SYSTEMS INC. DIV S  
 TRADE NAME INTUBATION ENDOSCOPE AND INTRODUCER SHEATH  
 COMMON NAME BRONCHOSCOPE, TRACHEA AND LUNGS #DE  
 MODEL ID  
 PRODUCT CODE  
 REVIEW TIER EXPEDITED REVIEW S

BRANCH LOGIN

DATE LOGGED IN:

DMC 18-FEB-97  
 DIVISION 04-MAR-97  
 BRANCH 04-MAR-97  
 KEYWORDS

DATE DUE:

90TH DAY 19-MAY-97  
 90TH DAY 19-MAY-97  
 90TH DAY 19-MAY-97

COMMENTS  
 TEAM LEADER

<KP0> = Menu Bar | <KP.> = Action History | <F2> = Help | <F4> = Exit

Count: \*1

510(k)

	INITIALS	DATE IN	DATE OUT
Consumer Safety Tech. Log in	SFB	3/4	3/4
Group Leader	RNP		3/4
Reviewer	EXW	3/4	3/26
Consulting Review			
Consulting Review			
Secretary (typing)			
Reviewer sign-off			
Group Leader sign-off			
Maxine Brown proof read			
Director sign-off (NSE & Changes)			
Consumer Safety Tech. Log out			

ACTION ISSUE? \_\_\_\_\_

KEY WORDS FOR SEARCH PURPOSES

PRODUCT CODE \_\_\_\_\_ CLASS \_\_\_\_\_



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 8 1997

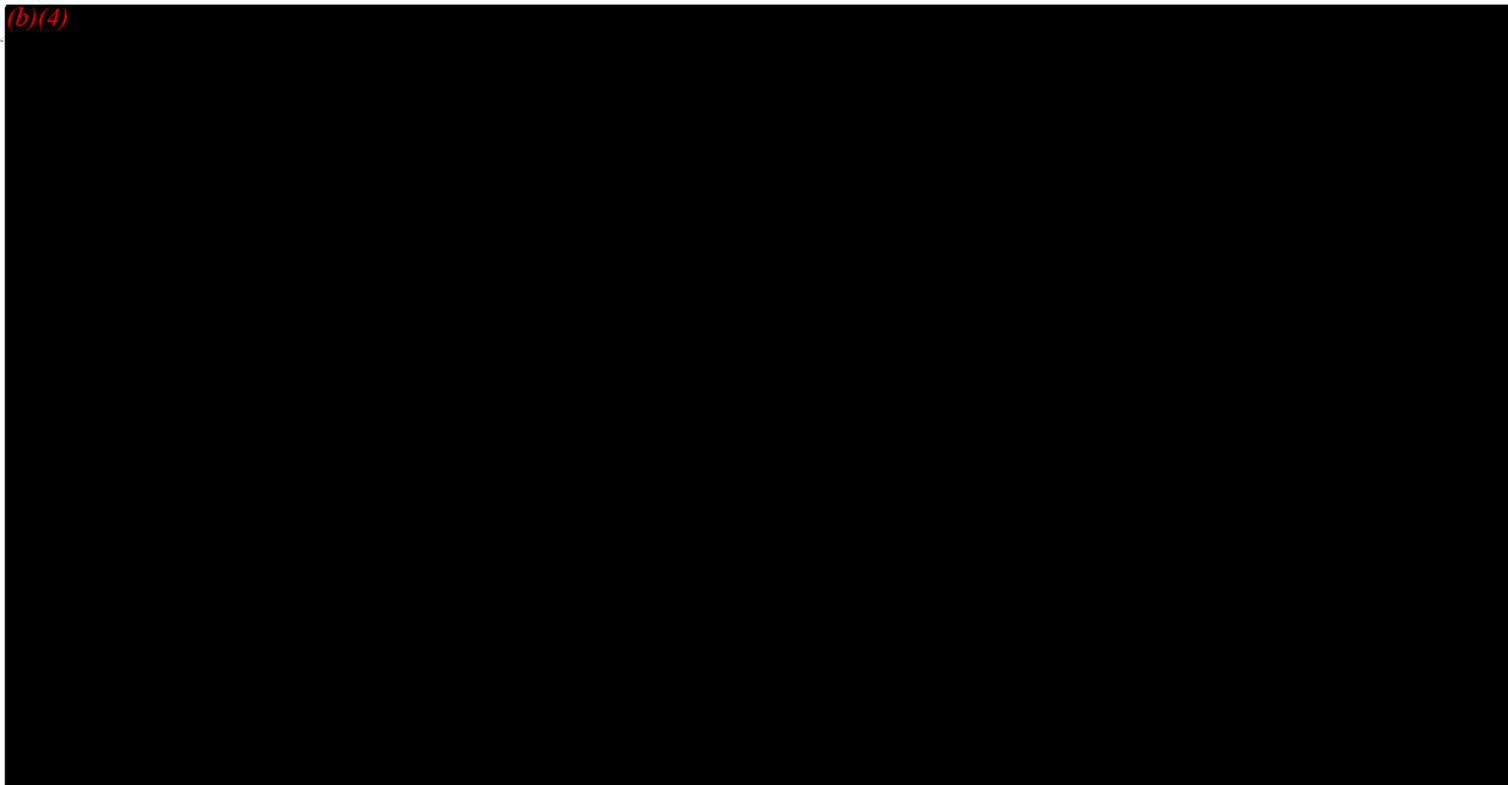
Ronald Bergeson  
Corporate Director, Regulatory Affairs  
UroHealth  
3050 Redhill Avenue  
Costa Mesa, CA 92626

Re: K970107  
Intubation Endoscope and Introducer Sheath  
Dated: February 17, 1997  
Received: February 18, 1997

Dear Mr. Bergeson:

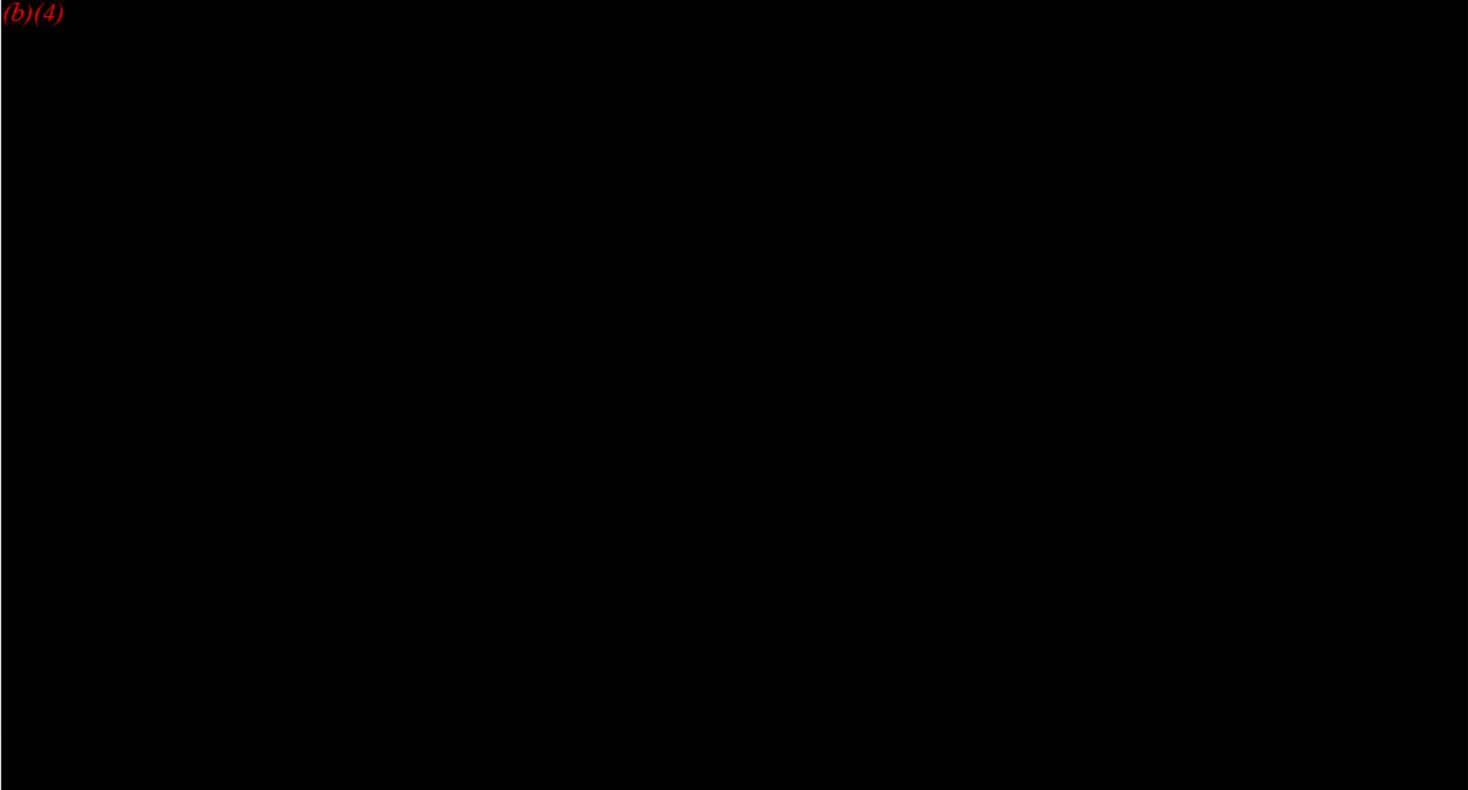
We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following information:

(b)(4)



Page 2 - Ronald Bergeson

(b)(4)



We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), 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 Federal Food, Drug, and Cosmetic Act (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.

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); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

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:

73

Page 3 - Ronald Bergeson

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact Karen Baker at (301) 594-2080. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,



Harry Sauberman, P.E.  
Chief, Ear, Nose and Throat Branch  
Office of Device Evaluation  
Center for Devices and  
Radiological Health



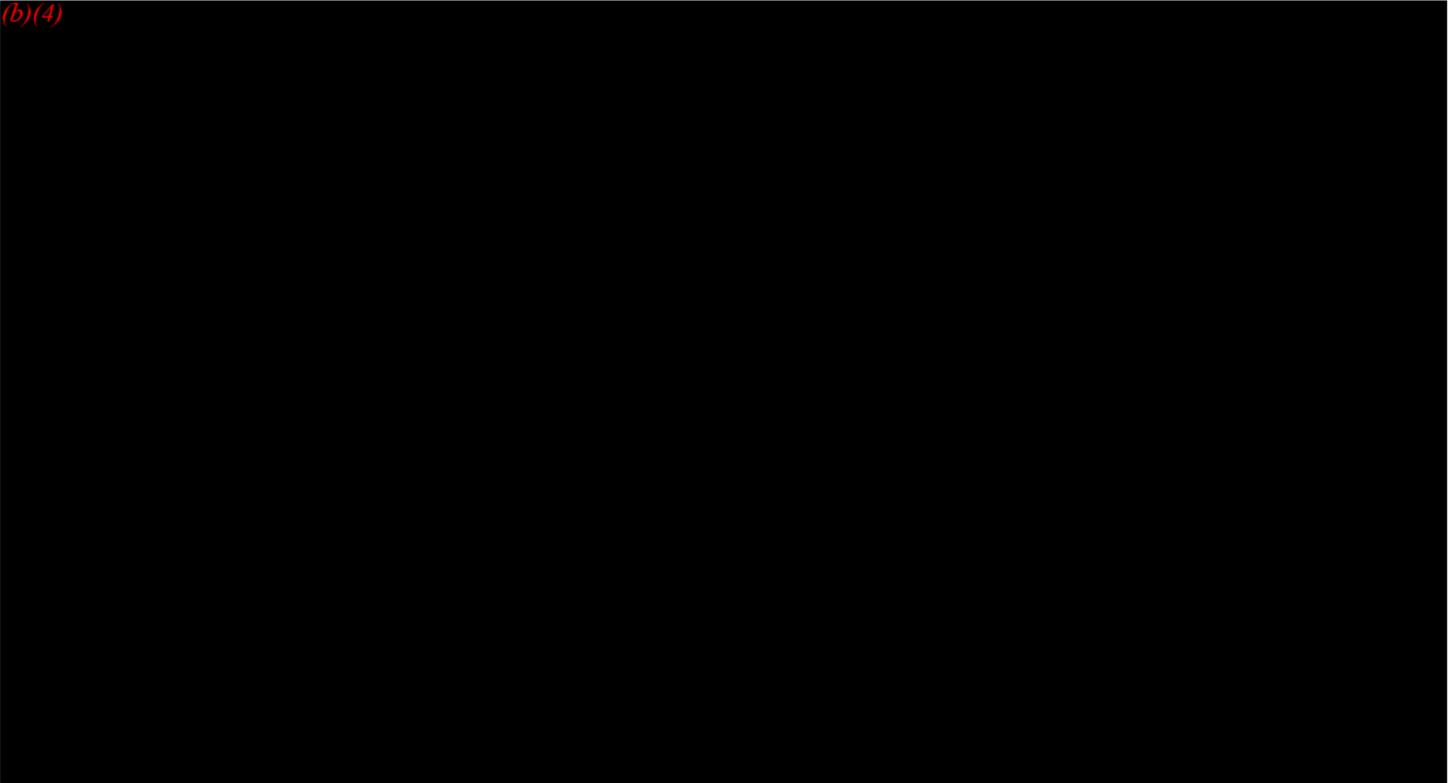
Ronald Bergeson  
Corporate Director, Regulatory Affairs  
UroHealth  
3050 Redhill Avenue  
Costa Mesa, CA 92626

Re: K970107  
Intubation Endoscope and Introducer Sheath  
Dated: February 17, 1997  
Received: February 18, 1997

Dear Mr. Bergeson:

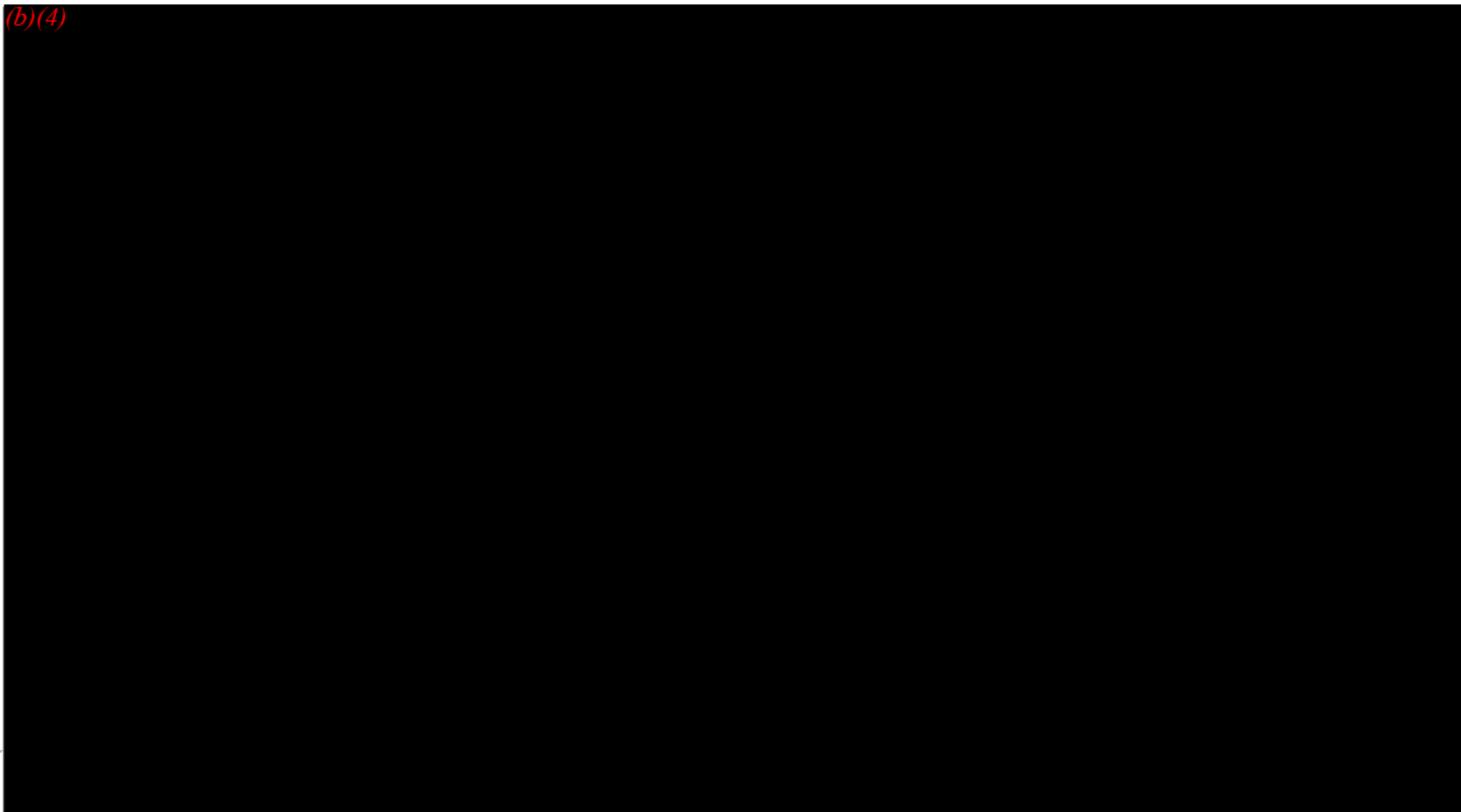
We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following information:

(b)(4)



Page 2 - Ronald Bergeson

(b)(4)



We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), 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 Federal Food, Drug, and Cosmetic Act (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.

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); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

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:

Page 3 - Ronald Bergeson

Food and Drug Administration  
 Center for Devices and  
 Radiological Health  
 Document Mail Center (HFZ-401)  
 9200 Corporate Boulevard  
 Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact Karen Baker at (301) 594-2080. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "dsma@fdadr.cdrh.fda.gov".

Sincerely yours,

Harry Sauberman. P.E.  
 Chief, Ear, Nose and Throat Branch  
 Office of Device Evaluation  
 Center for Devices and  
 Radiological Health

cc: HFZ-401 DMC  
 HFZ-404 510(k) Staff  
 HFZ-470 Division  
 D.O.

Draft:cdba:4.4.97  
 Final:cdba:4.4.97

FILE  
 COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
2-470	Baker	4/18/97						
2-470	Sauberman	4/14						



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Karen H Baker

Subject: 510(k) Number K970107

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review 4/1/97
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?  YES  NO

Is this device subject to the Tracking Regulation?  YES  NO

Was clinical data necessary to support the review of this 510(k)?  YES  NO

Is this a prescription device?  YES  NO

Was this 510(k) reviewed by a Third Party?  YES  NO

This 510(k) contains:

- Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 307.95 (doesn't apply for SEs):

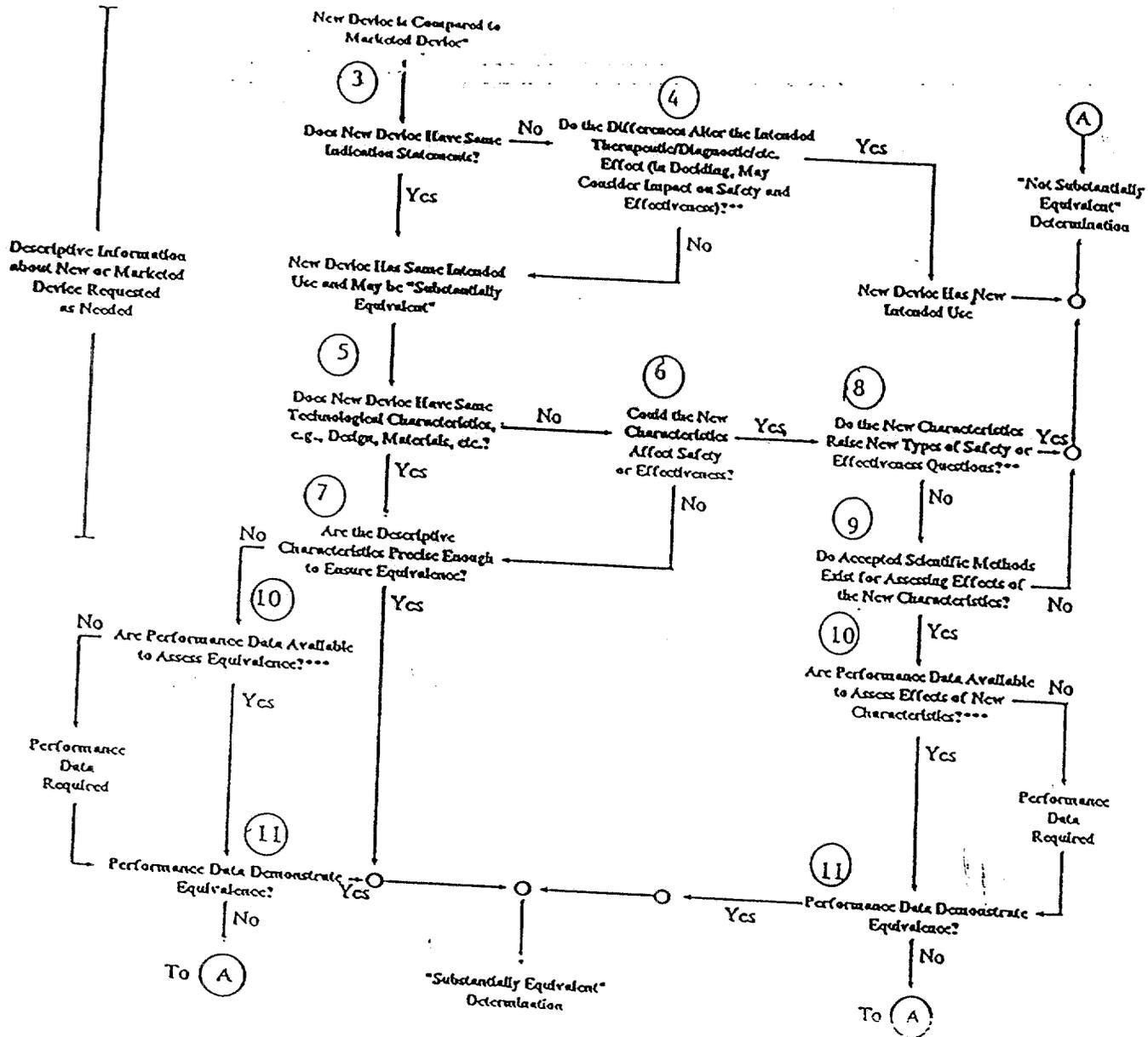
- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: 874.4680 77 E09 Class I Additional Product Code(s) with panel (optional):

Review: [Signature] ENTB 4/4/97  
(Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_  
(Division Director) (Date) 78

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



- 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.

**DRAERD REVIEWER RECORD FOR ORIGINAL 510(K)S,  
AND PMA AND IDE SUPPLEMENTS**

Document No. K970107 Reviewer Karen Baker Date Assigned 4/1/97

**CONSULTING REVIEWS DESIGNATED, AS APPROPRIATE, BY BRANCH CHIEF AND LEAD REVIEWER, AT THE BEGINNING OF THE REVIEW:**

<u>SPECIALTY</u>	<u>REVIEW NEEDED?</u>		<u>REVIEWER</u>	<u>DATES</u>	
	YES	NO		SENT	RETURNED
CLINICAL	_____	_____	_____	_____	_____
ENGINEERING/ PHYSICS	_____	_____	_____	_____	_____
CHEMISTRY/ BIOMATERIALS	_____	_____	_____	_____	_____
SOFTWARE	_____	_____	_____	_____	_____
BIOLOGICAL/ STERILITY	_____	_____	_____	_____	_____
TOXICOLOGY/ BIOCOMPATIBILITY	_____	_____	_____	_____	_____
STATISTICS	_____	_____	_____	_____	_____
OTHER _____	_____	_____	_____	_____	_____

**COMMENTS:**

*This document was sent to DCRPD for review (2-21-97) should be reviewed by anesthesia branch. It was returned 3/20/97. Karen Baker. This was due to the intended use of information. DCRPD - refused the document with request that ENT review it. Karen Baker*

**REVISED 1/2/96 LMS  
ON LAN AS REVREC.FRM**

80

RRG 9/24/93  
Rev. 5/8/95

**FOR REVIEWER'S USE ONLY**  
**DRAERD Premarket Notification 510(k)**  
**SUPPLEMENTAL Screening Checklist**

DRAERD has been given the go ahead to continue with the DRAERD Premarket Notification 510(k) Screening Checklist program rather than switching to the ODE Premarket Notification (510(k)) Checklist for Acceptance Decision. However, some items appear in the ODE Checklist that were not in the early version of the DRAERD Checklist or Explanation of the Checklist. Therefore, the following items should be included as part of the DRAERD screening process:

510(k) Number: K970107 TIER (Circle) I/II/III

Expedited Review Requested: Y/N Granted: Y/N OR, FDA Identified Expedited: Y/N

ITEM	<u>Yes</u>	<u>No</u>
1. Is the product a device?	✓	-
2. Is the device exempt from 510(k) by regulation or policy?	-	✓
3. Are you aware that this device has been the subject of a previous NSE decision? If yes, does this new 510(k) address the NSE Issue(s) (e.g., performance data)?	-	✓
4. Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer, and has the ODE Integrity Officer given permission to proceed with the review?	-	✓
5. Is there a specific guidance document for this device or device issue(s)?	-	✓
6. Is this a file that was determined to be substantially equivalent (SE) by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? If yes, a new review by ODE is not required, please forward to POS.	-	✓

In addition, the following item is going to be required as part of a revision to the 510(k) regulation. However, it is not required now, but the Explanation of the DRAERD Screening Checklist has been modified to include this information.

7. Address of manufacturing facility/facilities, and if applicable, sterilization site(s).

Administrative Reviewer Signature: Karen Bolin Date: 4/1/97 81

QUALITY CONTROL OVERVIEW OF DOCUMENT

A. ASSOC. DIRECTOR QC OVERVIEW: MEDICAL QC OF SUBMISSION IS NECESSARY?

YES \_\_\_\_\_ NO \_\_\_\_\_ INITIALS/Date \_\_\_\_\_

B. IF YES IS NOTED ABOVE, MEDICAL OFFICER QC OVERVIEW:

1. Examination of the specialty reviews indicate there are remaining clinical issues that should be addressed (See attached sheet for summary).

INITIALS/Date \_\_\_\_\_

2. In my opinion, all pertinent clinical issues have been adequately addressed.

FINAL SIGNOFF: MEDICAL OFFICER/DATE \_\_\_\_\_

FINAL SIGNOFF: ASSOC. DIRECTOR/DATE \_\_\_\_\_

REVISED: 1/2/96 LMS  
LOCATED ON LAN AS REVREC.FRM

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

**Document #** K970107

**Company Name:** UroHealth  
3050 Redhill Avenue  
Costa Mesa, CA 92626  
(714)708-7748  
FAX (714)708-7795

**Contact Person:** Ronald Bergeson  
Corporate Director, Regulatory Affairs

**Device Name:** Intubation Endoscope and Introducer Sheath

**CLASSIFICATION NAME:** Bronchoscope and accessories  
**COMMON NAME:** Bronchoscope, rigid or flexible

**PRODUCT TO WHICH COMPARED:** (510(k) NUMBER IF KNOWN)

SteBar Instrument Corp, Schroeder Oral/Nasal Stylette  
Vision Sciences, EndoSheath - K961591  
American Optical, Flexible Bronchoscope FBS-1 - K811181  
Karl Storz, Intubation Fiberscope - K961178

**INTENDED USE STATEMENT:**

The Intubation Endoscope is intended to provide visualization in the trachea and lungs during fiberoptically assisted intubation and airway management.

SB

K970107, page 2.

- |  | YES | NO |                                   |
|--|-----|----|-----------------------------------|
| 1. IS PRODUCT A DEVICE?  | X   |    | - IF NO STOP                      |
| 2. DEVICE SUBJECT TO 510(k)?   | X   |    | - IF NO STOP                      |
| 3. SAME INDICATION STATEMENT?  | X   |    | - IF YES GO TO 5                  |
| 4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS? |     |    | - IF YES STOP<br>- NE             |
| 5. SAME TECHNOLOGICAL CHARACTERISTICS?   | X   |    | - IF YES<br>- GO TO 7             |
| 6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?                   |     |    | - IF YES GO TO 8                  |
| 7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?                                     |     | X  | - IF NO GO TO 10<br>- IF YES STOP |
| 8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?                                 |     |    | - IF YES STOP<br>- NE             |
| 9. ACCEPTED SCIENTIFIC METHODS EXIST?  |     |    | - IF NO STOP<br>- NE              |
| 10. PERFORMANCE DATA AVAILABLE?  |     | X  | - IF NO REQUEST DATA              |
| 11. DATA DEMONSTRATE EQUIVALENCE?  |     |    |                                   |

**Submission Provides**

Comparative Specifications:	yes
Comparative Lab Data:	no
Summary of Animal Testing:	no
Summary of Clinical Testing:	no
510(K) Statement:	no
510(K) Summary:	ye

K970107, page 3.

## GENERAL INFORMATION SUMMARY

Life-Supporting or Life-Sustaining:	no
Is it an Implant?	no
Software Driven:	no
Level of Concern Certification	
Sterility: (single use sheath)	yes
Single Use:	
Disposable sheath	yes
Bronchoscope	no
Home or prescription use:	yes
Drug or Biologic product:	no
Device a kit:	no

Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the device design, materials, physical properties and toxicology profile if important.

## A. Device Description:

The Intubation Endoscope and Introducer Sheath system is comprised of two main components; a fiberoptic endoscope and an introducer sheath. The endoscope is inserted into the sheath and consists of a focusing ocular lens, a distal objective lens, optical and light fibers and a connection for a fiber optic light cable.

The introducer sheath consists of two channels, one for insufflation of oxygen and fluids, and one for scope insertion. The introducer sheath also has a mechanism to deflect the distal tip. The distal tip also contains a window through which the endoscope views the trachea and lungs. There are two models of introducer sheath; one that is malleable which contains a stainless steel wire to maintain the shape that is contoured by the physician for the patient's anatomy and, one that is nonmalleable which still contains a stainless steel wire but the wire is not malleable.

## B. Device Materials and Toxicity

The sponsor states that there are no patient contacting components in the fiberoptic scope.

85

K970107, page 4.

The patient contacting components in the introducer sheath are:

1. Bonding material - [redacted], (b)(4) [redacted] Product Specificati
2. Distal tip - [redacted], (b)(4) [redacted]
3. Pull tube - (b)(4) [redacted]
4. Handle housing - (b)(4) [redacted]
5. Female leu - (b)(4) Product [redacted]
6. Distal window - [redacted], (b)(4) Product [redacted]
7. Lumen body tubing - [redacted], (b)(4) [redacted]
8. Malleable wire - (b)(4) [redacted] P d
9. Scope tubing - (b)(4) [redacted]
10. Thumb lever - [redacted] e (b) [redacted] (4)

The sponsor states that biocompatibility testing will be conducted on both component level and finished devices (sterile, if applicable). This testing will include but is not limited to cytotoxicity, sensitization and irritation. This device is considered body contact surface of mucosal membranes for a limited contact duration (less than 24 hours). This testing is in accordance with EN 30993 for medical devices.

C. Comparative Specifications

The sponsor includes a chart comparing the subject and predicate devices in terms of: tip deflection; deflection method; overall and working length; distal diameter; presence of an instrument or flushing channel; presence of a malleable sheath and biocompatibility.

No description of optics or image quality is presented or compared. Overall diameter of the Insertion Sheath is not presented or compared.

D. Physical Properties and Performance Testing

Physical properties are described in terms of materials of the Introducer Sheath and the endoscope.

No testing of optical or image quality is presented.

No testing to demonstrate the microbial barrier properties of the sheath materials is presented.

K970107, page 5.

E. Clinical Testing

No clinical testing is presented.

F. Sterilization

The sponsor states that both Gamma and ETO sterilization may be utilized. They further stated that validation will be accomplished per ANSI/AAMI/ISO guidelines for medical products. An overkill approach will be completed with a sterility assurance level (SA) of  $10^{-6}$ .

The sterile single use package will be a Tyvek to PET/LDPE laminated pouch sealed by conventional methods.

G. Device Labeling

Proposed package labeling for the Malleable Introducer Sheath, (single unit and ten unit package); Nonmalleable Introducer Sheath (single unit and ten unit package); and Intubation Endoscope are included. The package labels (except Intubation Endoscope) include the statements that the devices are for single patient use, are sterile and provide the caution that the devices are restricted to sale by the order of a physician.

Also provided is sample instructions for use. These instructions do not provide any information for reprocessing of the Intubation Endoscope, the reusable portion of the device.

H. 510(K) Summary or Statement

A 510(k) Summary is provided.

SUMMARY:

This device consists of a reusable fiberoptic endoscope called the Intubation Endoscope and a sterile, disposable Introducer Sheath (malleable and nonmalleable).

The Intubation Endoscope is inserted into the Introducer Sheath and consists of a focusing ocular lens, a distal objective lens, optical and light fibers and a connection for a fiber optic light cable. A video system may be connected to the optical coupler or direct visualization may be performed.

K970107, page 6.

The Introducer Sheath consists of two channels, one for insufflation of oxygen and fluids, and one for scope insertion. The Introducer Sheath also has a mechanism to deflect the distal tip. The distal tip contains a window through which the endoscope views the trachea and lungs. There are two models of Introducer Sheath; one that is malleable which contains a stainless steel wire to maintain the shape that is contoured by the physician for the patient's anatomy and, one that is nonmalleable which still contains a stainless steel wire but the wire is not malleable.

Although it is not explicitly stated, the labeling suggests that use of the sheath system will prevent penetration of body fluids and microorganisms on to the Intubation Endoscope. The sponsor states "...the malleable sheath will be tested to ensure the sterile barrier is maintained during the entire procedure under normal usage conditions." The instructions direct the user to discard the disposable Introducer Sheath system and to store the Intubation Endoscope without any cleaning or disinfection after use.

It has been the policy of the Ear, Nose and Throat Branch that manufacturers of ENT endoscope sheaths claiming protective barrier properties must support this claim with laboratory data demonstrating the device to be impermeable to penetration by microorganisms. In addition, reprocessing of the endoscope after removal of the used sheath must be recommended and described in the user's information material. If the sponsor sufficiently demonstrates protective barrier properties of the finished device, a cleaning procedure followed by an intermediate disinfection step is sufficient. If the sponsor does not demonstrate protective barrier properties of the finished device, a cleaning procedure followed by high level disinfection is required. ✓

The sponsor will be referred to the CDRH Guidance for the Content of Premarket Notification for Disposable, Sterile, Ear, Nose and Throat Endoscope Sheaths with Protective Barrier Claims for additional information on testing of sheaths as barriers to microorganisms and for reprocessing instructions.

The sponsor does not provide complete information regarding technical and optical qualities of Intubation Endoscope. The sponsor is asked to provide additional description of the system, such as: field of view, direction of observation, range of focus, diameter of the insertion tube, articulation, and optical characteristics.

This reviewer is unable to make a determination of substantial equivalence based on the information provided by the sponsor, therefore, additional information is requested. 88

K970107, page 7.

RECOMMENDATION:

The sponsor will be asked to provide the following in an additional information letter. ✓

1. Appendix H in the submission, states "Functional performance testing of the sheath will be performed to verify maintenance of the sterile barrier under normal usage conditions." This and other statements throughout the submission suggest that the sheath will perform as a barrier to microorganisms and body fluids.

It has been the policy of the Ear, Nose and Throat Devices Branch to require manufacturers of ENT endoscope sheaths claiming protective barrier properties to support such claims with laboratory test data demonstrating the device to be impermeable to penetration by fluids and microorganisms. Appropriate microbial barrier testing should be completed and submitted to FDA. The sponsor is referred to the Guidance for the Content of Premarket Notifications for Disposable, Sterile, Ear, Nose and throat endoscope Sheaths with Protective Barrier Claims.

2. It is implied that the barrier properties of the sheath will negate the need to clean or disinfect the Intubation Fiberscope after use. Although the endoscope is completely enclosed in the sheath there are multiple opportunities for break in asepsis or cross contamination. There should be a cleaning instruction for reprocessing of the endoscope portion after each use. The sponsor is referred to the Guidance for the Content of Premarket Notifications for Disposable, Sterile, Ear, Nose and Throat Endoscope Sheaths with Protective Barrier Claims. The sponsor is asked to provide sample labeling.

3. Complete technical and optical quality information for the Intubation Endoscope is not provided. The sponsor is asked to provide additional description of the system, such as: diameter of the Introducer Sheath at its widest point; optical characteristics such as field of view, depth of view, distortion, light transmission and image quality. Sample labeling should be provided.

4. It is unclear whether fiberoptic endoscopes made by other manufacturers would be compatible with the Introducer Sheath or if only the Intubation Endoscope can be used. If other endoscopes can be used they should be listed in the user's instructions. If only the Intubation Endoscope is compatible, that should be stated. Will use of other endoscopes damage the Introducer Sheath? If so, a caution should be included to warn the user against trying to use other endoscopes with the system. Sample labeling should be provided.

K970107, page 8.

CFR# 874.4680  
Product Code 77-EOO  
CLASS II

Karen Baker  
-----  
Karen H. Baker RN, MSN

4/4/97  
-----  
Date

4/4/97  
4/4/97

90

RRG/LLD 1/6/93  
Rev. 2/6/96

**DRAERD Premarket Notification 510(k)  
Screening Checklist**

510(k) Number & Device Name K970107 Indubation indwager and  
introducer sheath  
Company Arthrohealth

ITEM	PRESENT		NEEDED (Y/N/?)
	Yes	No	
1. General information ( i.e., trade & classification name, Est. Reg. No., device class, meets special controls or a performance standards, etc.)	/	-	-
Reason for 510(k) - new device or modification	/	-	-
Identification of legally marketed equivalent device	/	-	-
Truthful and accurate statement	/	-	-
SMDA 510(k) <u>summary</u> or statement	/	-	-
2. Proposed Labeling, Labels, Advertisements	/	-	-
Description of new device/modification	/	-	-
Intended use statement	/	-	-
Diagrams, Engineering Drawings, Photographs	/	-	-
Indication for Use Statement	/	-	-
3. Comparison of similarities/differences to named legally marketed equivalent device	/	-	-
Equivalent Device Labeling, Labels, Advertising	/	-	-
Intended use of equivalent device	/	-	-
4. List of all patient contacting materials in new device	/	-	-
Comparison of materials to equivalent device	-	-	-
5. Biocompatibility information/data for patient contacting materials, OR Certification - identical material/formulation	-	-	-
6. Performance data: Bench data	-	/	yes
Animal data	-	/	-
Clinical data	-	/	-
7. Sterilization information	-	/	-
8. Software validation & verification	-	/	-
9. If Class III, Class III Certification & Summary	-	/	-
10. If kit, kit certification	-	/	-

*If screening  
was done  
naturally, done  
by me & may  
have failed  
screening.  
However it was  
in scope & for a  
while & was its  
too late to fail.  
an AI letter  
will be sent.  
K970107  
9/1/97*

*Class III  
reusable  
for patient use  
Padded  
91*

---

MEMO TO THE RECORD

From: Emil Wang

ODE/DCRND/ADDG

Date: March 26, 1997

To: K970107

Subject: UROHEALTH Intubation Endoscope and Introducer Sheath

Sponsor: UROHEALTH Systems, Inc.

---

This 510(k) Notification was originally classified by the sponsor under the following device classification: 874.4680, Bronchoscope (flexible or rigid) and accessories. However, this submission was routed to DCRND/ADDG under the following classifications: 868.5530 (Flexible laryngoscope) and 868.5540 (Rigid laryngoscope). In my review of this 510(k) Notification, I compared this device's intended use and device characteristics to the claimed predicate devices (Appendix I). I have enclosed IMAGE copies of K961591 & K961178. The claimed predicate devices were all reviewed and cleared under the classification for 874.4680. In addition, the subject device's characteristics are not consistent with those laryngoscopes reviewed by DCRND/ADDG. Therefore, I recommend that this file should be re-routed to the ENT panel under the classification for Bronchoscope and accessories, 874.4680.



3/26/97

---

Emil Wang  
Biomedical Engineer

92

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

February 18, 1997

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

UROHEALTH SYSTEMS INC.  
3050 REDHILL AVE.  
COSTA MESA, CA 92626  
ATTN: RONALD H. BERGESON

510(k) Number: K970107  
Product: INTUBATION  
ENDOSCOPE AND  
INTRODUCER  
SHEATH

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 (HFZ-401) 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. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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 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.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

93



# UROHEALTH

February 17, 1997

RECEIVED

18 FEB 97 10 05

FDA/CDRH/ODE/DMC

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

Re: 510(k) Premarket Notification K970107  
UROHEALTH Systems, Inc.  
Intubation Endoscope and Introducer Sheath  
"INDICATION FOR USE" Form

Dear Sir or Madam:

Thank you for notifying us of the need to provide FDA with an "Indication for Use" form with this, and all premarket notifications. In follow up to your request, dated January 14, 1997, enclosed is a copy of the completed "Indication for Use" form. This form will be included in all future premarket notifications.

Should you have any questions pertaining to this form, or the premarket notification please contact me at (714) 708-7748, extension 248.

Sincerely,

Ronald H. Bergeson  
Corporate Director, Regulatory Affairs  
UROHEALTH Systems, Inc.

SK 2/18

gn

510 (k) Number (if known): K970107

Device Name: Intubation Endoscope and Introducer Sheath

Indications for Use:

The Intubation Endoscope is used for direct visualization in the trachea and lungs during fiberoptically assisted intubation and airway management.

(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 801.1091)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

January 30, 1997

UROHEALTH SYSTEMS INC.  
3050 REDHILL AVE.  
COSTA MESA, CA 92626  
ATTN: RONALD H. BERGESON

510(k) Number: K970107  
Product: INTUBATION  
ENDOSCOPE AND  
INTRODUCER  
SHEATH

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) 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. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Supervisor Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

K970107



January 10, 1997

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, MD 20850

RECEIVED  
13 JUN 97 12 52  
FDA/CDRH/ODE/DMG

Re: 510(k) Premarket Notification  
UROHEALTH Systems, Inc.  
Intubation Endoscope and Introducer Sheath

Dear Sir or Madam:

In accordance with Section 510(k) of the Food, Drug and Cosmetic Act, UROHEALTH Systems, Inc. (hereafter UROHEALTH) submits in duplicate this premarket notification for the UROHEALTH Systems, Inc. Intubation Endoscope and Introducer Sheath .

A Summary of Safety and Effectiveness is provided within this submission. The Premarket Submission Cover Sheet and the DRAERD Screening Checklist are also provided for the Reviewer's convenience.

UROHEALTH will not begin marketing this device until we have received a letter from the Food and Drug Administration clearing this device for sale and marketing.

Sincerely,

Ronald H. Bergeson  
Corporate Director, Regulatory Affairs  
UROHEALTH Systems, Inc.

SK37

97 EN

**PREMARKET NOTIFICATION  
510(k)**

Device Name: Intubation Endoscope and Introducer Sheath  
(Name to be changed)

Common Name: Bronchoscope, Trachea and Lungs

Classification Name: Bronchoscope, Flexible or Rigid

Panel: Ear, Nose and Throat

Establishment Registration Number: 2082063  
UROHEALTH Systems Inc.  
Costa Mesa, CA

Device Classification: Class II  
874.4680

Action taken to register to comply with the requirements of the Act under Section 514 for performance standards: No standards for this device have been promulgated under section 514 of the Act.

*868.5530  
Flexible  
bronchoscope  
868.5540  
Rigid  
bronchoscope*

**Product Description**

The Intubation Endoscope and Introducer Sheath is comprised of two main components; a fiberscope and an introducer sheath. The fiberscope is inserted into the introducer sheath and consists of a focusing ocular lens, a distal objective lens, optical and light fibers, and a connection for a fiber optic light cable.

The introducer sheath consists of two channels; one for insufflation of oxygen and fluids, and one for scope insertion. The introducer sheath also has a mechanism to deflect the distal tip. The distal tip also contains a window through which the fiberscope views the trachea and lungs. There are two models of introducer sheath; one that is malleable which contains a stainless steel wire to maintain the shape that is contoured by the physician for the patient's anatomy; and, one that is nonmalleable which still contains a stainless steel wire but the wire is not malleable.

*98*

**TABLE OF CONTENTS**

<b><u>APPENDIX</u></b>	<b><u>ITEM</u></b>	<b><u>PAGE</u></b>
A	PREMARKET SUBMISSION COVERSHEET	1
B	SCREENING CHECKLIST	6
C	PROPOSED LABELS - INTRODUCTION	8
C-1	INTUBATION ENDOSCOPE MALLEABLE SHEATH SINGLE UNIT PACKAGE	9
C-2	INTUBATION ENDOSCOPE NONMALLEABLE SHEATH SINGLE UNIT PACKAGE	10
C-3	INTUBATION ENDOSCOPE MALLEABLE SHEATH TEN UNIT PACKAGE	11
C-4	INTUBATION ENDOSCOPE NONMALLEABLE SHEATH TEN UNIT PACKAGE	12
C-5	FLEXIBLE INTUBATION ENDOSCOPE PACKAGE LABEL	13
D	PROPOSED INSTRUCTIONS FOR USE	14
E	PRODUCT DRAWINGS	19
F	PROPOSED ADVERTISING AND PROMOTIONAL COPY	22

**TABLE OF CONTENTS (continued)**

<b><u>APPENDIX</u></b>	<b><u>ITEM</u></b>	<b><u>PAGE</u></b>
G	COMPETITIVE MARKETING LITERATURE	24
G-1	SteBar Instr. Corp. Schroeder Oral/Nasal Stylette™	25
G-2	VISION-SCIENCES EndoSheath®	28
G-3	American Optical Flexible Bronchoscope FBS-1	31
G-4	Karl Storz Intubation Fiberscope	37
H	SUBSTANTIAL EQUIVALANCE	39
I	COMPARISON TABLE	40
J	PATIENT CONTACTING MATERIALS AND BIOCOMPATIBILITY	45
K	PERFORMANCE TESTING, STERILIZATION, AND PACKAGING	46
L	510(k) SUMMARY	47
M	TRUTHFUL AND ACCURATE STATEMENT	

100

**APPENDIX A**

**PREMARKET SUBMISSION COVERSHEET**

101  
000001

## CENTER FOR DEVICES AND RADIOLOGICAL HEALTH Premarket Submission Cover Sheet

Date of Submission:

FDA Document Number:

### Section A Type of Submission

- |   |   |  |   |
|---|---|--|---|
| <input checked="" type="checkbox"/> 510(k)        | <input type="checkbox"/> IDE            | <input type="checkbox"/> PMA           | <input type="checkbox"/> PMA Supplement - Regular     |
| <input type="checkbox"/> 510(k) Add'l information | <input type="checkbox"/> IDE Amendment  | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement - Special     |
|   | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> PMA Report    | <input type="checkbox"/> PMA Supplement - 30 day      |
|   | <input type="checkbox"/> IDE Report     |  | <input type="checkbox"/> PMA Supplement - Panel Track |

### Section B1 Reason for Submission — 510(k)s Only

- New device  Additional or expanded indications  Change in technology, design, materials, or manufacturing process
- Other reason (specify):

### Section B2 Reason for Submission — PMAs Only

- |   |   |   |
|---|---|---|
| <input type="checkbox"/> New device<br><input type="checkbox"/> Withdrawal<br><input type="checkbox"/> Additional or expanded indications<br><input type="checkbox"/> Licensing agreement<br><br><input type="checkbox"/> Labeling change:<br><input type="checkbox"/> Indications<br><input type="checkbox"/> Instructions<br><input type="checkbox"/> Performance Characteristics<br><input type="checkbox"/> Shelf life<br><input type="checkbox"/> Trade name<br><input type="checkbox"/> Other (specify below)<br><br><input type="checkbox"/> Change in ownership<br><input type="checkbox"/> Change in correspondent<br><br><input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Change in design, component, or specification:<br><input type="checkbox"/> Software<br><input type="checkbox"/> Color Additive<br><input type="checkbox"/> Other (specify below)<br><br><input type="checkbox"/> Process change:<br><input type="checkbox"/> Manufacturer<br><input type="checkbox"/> Sterilizer<br><input type="checkbox"/> Packager<br><br><input type="checkbox"/> Response to FDA correspondence (specify below)<br><input type="checkbox"/> Response for applicant hold<br><input type="checkbox"/> Response for removal of applicant hold<br><input type="checkbox"/> Response for extension<br><input type="checkbox"/> Response for remove or add manufacturing site | <input type="checkbox"/> Location change:<br><input type="checkbox"/> Manufacturer<br><input type="checkbox"/> Sterilizer<br><input type="checkbox"/> Packager<br><input type="checkbox"/> Distributor<br><br><input type="checkbox"/> Report submission:<br><input type="checkbox"/> Annual or periodic<br><input type="checkbox"/> Post-approval study<br><input type="checkbox"/> Adverse reaction<br><input type="checkbox"/> Device defect<br><input type="checkbox"/> Amendment |
|---|---|---|

### Section B3 Reason for Submission — IDEs Only

- |   |  |   |
|---|--|---|
| <input type="checkbox"/> New device<br><input type="checkbox"/> Addition of institution<br><input type="checkbox"/> Expansion / extension of study<br><input type="checkbox"/> IRB certification<br><input type="checkbox"/> Request hearing<br><input type="checkbox"/> Request waiver<br><input type="checkbox"/> Termination of study<br><input type="checkbox"/> Withdrawal of application<br><input type="checkbox"/> Unanticipated adverse effect<br><br><input type="checkbox"/> Emergency use:<br><input type="checkbox"/> Notification of emergency use<br><input type="checkbox"/> Additional information<br><br><input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Change in:<br><input type="checkbox"/> Correspondent<br><input type="checkbox"/> Design<br><input type="checkbox"/> Informed consent<br><input type="checkbox"/> Manufacturer<br><input type="checkbox"/> Manufacturing<br><input type="checkbox"/> Protocol—feasibility<br><input type="checkbox"/> Protocol—other<br><input type="checkbox"/> Sponsor<br><br><input type="checkbox"/> Report submission:<br><input type="checkbox"/> Current investigator<br><input type="checkbox"/> Annual progress<br><input type="checkbox"/> Site waiver limit reached<br><input type="checkbox"/> Final | <input type="checkbox"/> Response to FDA letter concerning:<br><input type="checkbox"/> Conditional approval<br><input type="checkbox"/> Deemed approval<br><input type="checkbox"/> Deficient final report<br><input type="checkbox"/> Deficient progress report<br><input type="checkbox"/> Deficient investigator report<br><input type="checkbox"/> Disapproval<br><input type="checkbox"/> Request extension of time to respond to FDA<br><input type="checkbox"/> Request meeting<br><br><input type="checkbox"/> IOL submissions only:<br><input type="checkbox"/> Change in IOL style<br><input type="checkbox"/> Request for protocol waiver |
|---|--|---|

000002

FDA Document Number:

**Section C Product Classification**

Product Code: **77E0Q** C.F.R. Section: **874.4680** Device class:  
 Class I  Class II  
 Class III  Unclassified

Classification panel:  
**EAR, NOSE AND THROAT**

**Section D Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:  
 1 **77E0Q** 2 **77SEJ** 3 4  
 5 6 7 8

Summary of, or statement concerning, safety and effectiveness data:  
 510(k) summary attached  
 510(k) statement

Information on devices to which substantial equivalence is claimed:

501(k) Number	Trade or proprietary or model name	Manufacturer
1 UNKNOWN	1 SCHROEDER ORAL/NASAL STYLETTE	1 STE BAR INSTR CORP
2 K961591	2 ENDOSHEATH	2 VISION SCIENCES
3 K811181	3 FLEXIBLE BRONCHOSCOPE	3 AMERICAN OPTICAL
4 K961178	4 INTUBATION FIBERSCOPE	4 KARL STORZ
5	5	5
6	6	6

**Section E Product Information — Applicable to All Applications**

Common or unusual name or classification name:  
**BRONCHOSCOPE, TRACHEA AND LUNGS**

Trade or proprietary or model name	Model Number
1 INTUBATION ENDOSCOPE AND INTRODUCER	1 N/A
2 SHEATH	2
3	3
4	4
5	5
6	6

FDA document numbers of all prior related submissions (regardless of outcome):

1 <b>K811181</b>	2 <b>K961178</b>	3 <b>K910423</b>	4 <b>K960876</b>	5 <b>K961178</b>	6
7	8	9	10	11	12

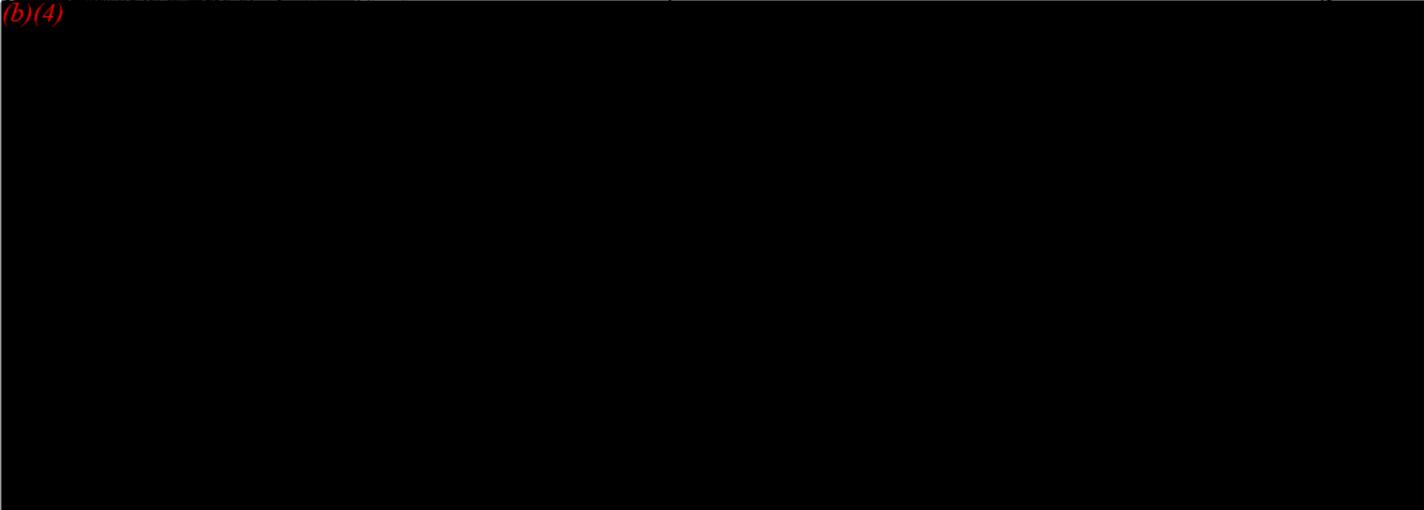
Data included in submission:  Laboratory testing  Animal trials  Human trials

Indications (from labeling):  
**DIRECT VISUALIZATION IN THE TRACHEA AND LUNGS DURING FIBEROPTICALLY ASSISTED INTUBATION AND AIRWAY MANAGEMENT.**

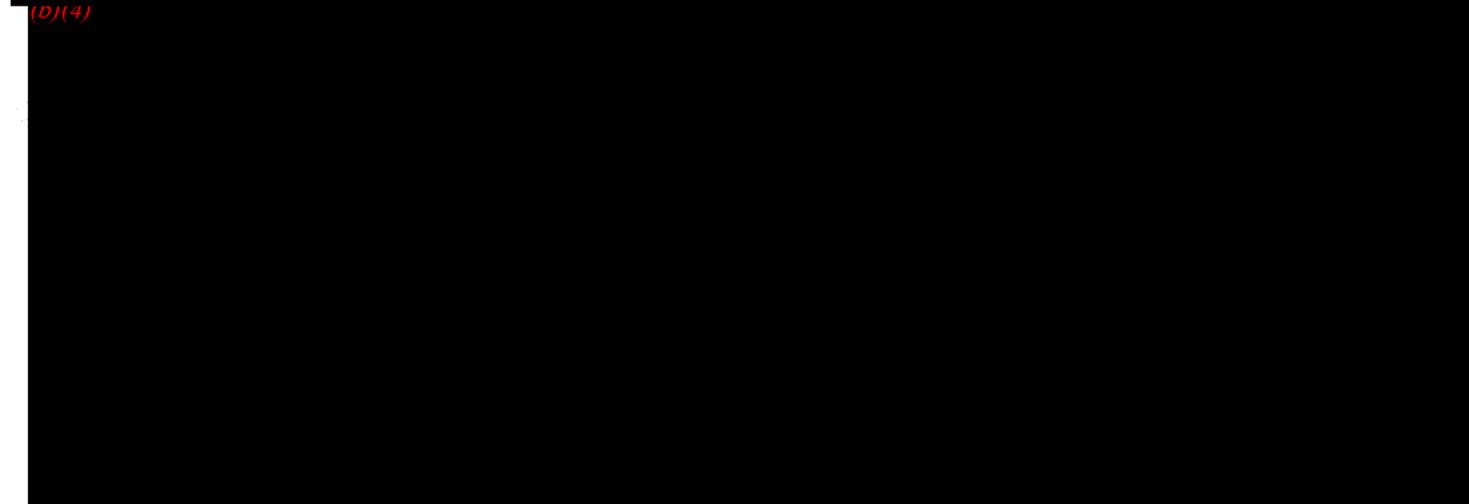
102  
000003

		FDA Document Number:
<b>Section F Manufacturing / Packaging / Sterilization Sites</b>		

<input checked="" type="checkbox"/> Original	FDA establishment registration number:	<input type="checkbox"/> Manufacturer	<input checked="" type="checkbox"/> Contract sterilizer
(b)(4)		<input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Repackager / relabeler



<input checked="" type="checkbox"/> Original	FDA establishment registration number:	<input checked="" type="checkbox"/> Manufacturer	<input checked="" type="checkbox"/> Contract sterilizer
(b)(4)		<input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Repackager / relabeler



<input type="checkbox"/> Original	<input type="checkbox"/> Add	<input type="checkbox"/> Delete	FDA establishment registration number:	<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer	<input type="checkbox"/> Repackager / relabeler
Company / Institution name:							
Division name (if applicable):					Phone number (include area code): (    )		
Street address:					FAX number (include area code): (    )		
City:		State / Province:		Country:		ZIP / Postal Code:	
Contact name:							
Contact title:							

000004  
h

				FDA Document Number:	
<b>Section G Applicant or Sponsor</b>					
Company / Institution name: UROHEALTH SYSTEMS, INC.			FDA establishment registration number: 208 2063		
Division name (if applicable):			Phone number (include area code): (714) 708-7748		
Street address: 3050 RED HILL AVE			FAX number (include area code): (714) 708-7795		
City: COSTA MESA	State / Province: CA	Country:	ZIP / Postal Code: 92626		
Signature: <i>Ronald H. Bergeson</i>					
Name: RONALD H. BERGESON					
Title: DIRECTOR OF REGULATORY AFFAIRS					
<b>Section H Submission correspondent (if different from above)</b>					
Company / Institution name:					
Division name (if applicable):			Phone number (include area code): ( )		
Street address:			FAX number (include area code): ( )		
City:	State / Province:	Country:	ZIP / Postal Code:		
Signature:					
Contact name:					
Contact title:					

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help the FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply only to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 635-2041 or (301) 443-6597.

105

**APPENDIX B**

**SCREENING CHECKLIST**

106

000006

Based on:

RRG/LLD 1/6/93

DRAERD Premarket Notification 510(k)

Rev. 3/14/95

Screening Checklist

**510(k) Number and Device Name:**

Intubation Endoscope and Introducer Sheath , K \_\_\_\_\_

**Company:** UROHEALTH Systems, Inc.

ITEM	PRESENT		NEEDED (Y/N?)
	Yes	No	
<b>1. General Information (i.e., trade &amp; classification name, Est. Reg. No., device class, meets special controls or a performance standard, etc.)</b>			
Reason for 510(k) - NEW DEVICE	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>Y</u>
Identification of legally marketed device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>Y</u>
Truthful and accurate statement	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>Y</u>
<b>2. Proposed labels, labeling</b>			
Description of new device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>Y</u>
Intended use statement	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>Y</u>
Diagrams, Engr. Dwgs, Photographs	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>Y</u>
<b>3. Comparison table and discussion</b>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>Y</u>
<b>4. List of all patient contacting materials</b>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>Y</u>
<b>5. Biocompatibility information for patient contacting materials.</b>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>Y</u>
<b>6. Performance Data: Bench</b>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>N</u>
Animal	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>N</u>
Clinical	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>N</u>
<b>7. Sterilization information</b>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>Y</u>
<b>8. Software validation &amp; verification</b>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>N</u>
<b>9. Summary of Safety and Effectiveness or Statement</b>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>Y</u>
<b>10. If Class III, Class III Certification &amp; Summary</b>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>N</u>
<b>11. If kit, kit certification</b>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>N</u>

107

## APPENDIX C

### PROPOSED LABELS

Draft copies of the package labels and the "Instructions for Use" follow this Tab.

No final promotional materials have been developed; however, a sample of proposed advertising copy is also presented in this section.

108  
000008

**APPENDIX C-1**

PROPOSED LABELING FOR

**INTUBATION ENDOSCOPE**  
**MALLEABLE INTRODUCER SHEATH**  
**SINGLE UNIT PACKAGE**

Intubation Endoscope Malleable Introducer Sheath

Sterile

Quantity One

Single Patient Use

For use with the Intubation Flexible Endoscope

Order Number NAV-101-1M

Part Number XXXX

Manufactured by UROHEALTH Systems Inc.

3050 Redhill Ave., Costa Mesa, CA 92626

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

109

000009

**APPENDIX C-2**

PROPOSED LABELING FOR

**INTUBATION ENDOSCOPE**  
**NONMALLEABLE INTRODUCER SHEATH**  
**SINGLE UNIT PACKAGE**

Intubation Endoscope Nonmalleable Introducer Sheath  
Sterile

Quantity One

Single Patient Use

For use with the Intubation Flexible Endoscope

Order Number NAV-101-1F

Part Number XXXX

Manufactured by UROHEALTH Systems Inc.

3050 Redhill Ave., Costa Mesa, CA 92626

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

110  
000010

**APPENDIX C-3**

PROPOSED LABELING FOR

**INTUBATION ENDOSCOPE**  
**MALLEABLE INTRODUCER SHEATH**  
**TEN UNIT PACKAGE**

Intubation Endoscope Malleable Introducer Sheath  
Sterile

Quantity Ten

Single Patient Use

For use with the Intubation Flexible Endoscope

Order Number NAV-101-10M

Part Number XXXX

Manufactured by UROHEALTH Systems Inc.

3050 Redhill Ave., Costa Mesa, CA 92626

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

000011

**APPENDIX C-4**

PROPOSED LABELING FOR

**INTUBATION ENDOSCOPE**  
**NONMALLEABLE INTRODUCER SHEATH**  
**TEN UNIT PACKAGE**

Intubation Endoscope Nonmalleable Introducer Sheath

Sterile

Quantity Ten

Single Patient Use

For use with the Intubation Flexible Endoscope

Order Number NAV-101-10F

Part Number XXXX

Manufactured by UROHEALTH Systems Inc.

3050 Redhill Ave., Costa Mesa, CA 92626

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

**APPENDIX C-5**

PROPOSED LABELING FOR

**INTUBATION ENDOSCOPE PACKAGE LABEL**

Intubation Flexible Endoscope

Quantity One

Order Number NAV-100

Part Number XXXX

Manufactured by UROHEALTH Systems Inc.

3050 Redhill Ave., Costa Mesa, CA 92626

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

**APPENDIX D**

PROPOSED INSTRUCTIONS FOR USE FOLLOW THIS PAGE

11/2  
000014

## INSTRUCTIONS FOR USE

### MALLEABLE (OR NONMALLEABLE) INTUBATION ENDOSCOPE AND INTRODUCER SHEATH

#### INDICATIONS FOR USE

The Intubation Endoscope is used for direct visualization in the trachea and lungs during fiberoptically assisted intubation and airway management.

#### PRIOR TO USE

In addition to thoroughly reading this manual, also refer to the instruction manuals supplied with your light source, accessories and other ancillary equipment.

#### 1. PREPARATION AND INSPECTION OF EQUIPMENT

Refer also to the instruction manuals supplied with your light source, accessories and other ancillary equipment.

##### 1-1 PREPARATION OF THE INTUBATION ENDOSCOPE

- a. Carefully remove the Intubation Endoscope from the shipping and storage container.

Do not discard this container. It will be used for storing the Intubation Endoscope when not in use.

- b. Insert the optical connector of the Intubation Endoscope into the optical coupler.
- c. Plug your fiberoptic light cable into the light cable adapter on the fiberscope.
- d. Connect the fiberoptic light cable into the output socket of your light source and turn the light source on.
- e. If using a video system turn on your video camera, monitor and any ancillary recording equipment and connect the video camera to the Intubation Endoscope Optical Coupler.

0000 15 <sup>115</sup>

- f. Inspect the optical system
  - Turn the diopter adjustment ring until the fiber pattern is clearly focused.
  - Check to see if an object, approximately 30 mm away from the window, can be visualized clearly.

## 1-2 PREPARATION OF THE INTRODUCER SHEATH

NOTE: The Intubation (Malleable or Nonmalleable) Introducer Sheath is supplied sterile. Use appropriate aseptic technique to maintain sterility of the device prior to use.

- a. Using aseptic technique remove the sterile Intubation Introducer Sheath from its packaging.
- b. Inspect the surface of the sheath visually for any debris, bulges, or other irregularities.
- c. Run your finger tips over the whole length of the insertion tube checking for any protruding objects, internal looseness, or other irregularities.
- d. Make sure that the bending section bends smoothly and correctly (Malleable model only) for the patient's anatomy. Simultaneously inspect the outer surface of the bending section visually for any irregularity.
- e. Inspect the infusion port by injecting a small amount of sterile water and verify that water is emitted from the end of the sheath.

## 2. OPERATING THE INTUBATION ENDOSCOPE AND INTRODUCER SHEATH SYSTEM

This section describes the basic operation of the Intubation Endoscope and Introducer Sheath, and outlines a general procedure for endoscopy. The endoscopist should study the clinical factors involved in each procedure and decide on the technical details of the procedure for themselves.

- 2-1 Insert the non-sterile Intubation Endoscope into the sterile Intubation Sheath.
- 2-2 Verify that the Sheath and Endoscope are securely connected.
- 2-3 Make sure that the bending section bends smoothly and correctly for the patient's anatomy (Malleable model only).

2-4 USE WITH AN ENDOTRACHEAL TUBE.

Extensive training and experience in the use of endotracheal tubes for intubation is required before attempting use of the Intubation Endoscope.

- a. Insert the Intubation Introducer Sheath and Endoscope assembly into a sterile endotracheal tube such that the tip extends from the distal end of the endotracheal tube. Avoid insertion through the Murphy's eye as this will make visualization and removal of the Endoscope difficult.

Note: Use of a water soluble or local anesthetic lubricant may be used to facilitate Endoscope insertion and removal from the endotracheal tube.

- b. The Malleable Intubation Introducer Sheath and endotracheal tube assembly can be shaped to fit the contour of the anatomy. Shape the Intubation Introducer Sheath by bending the endotracheal tube until the desired shape is achieved.

Note: The Nonmalleable Introducer Sheath is used in the same manner as the Malleable Introducer Sheath except that it can not be pre-shaped to fit the contour of the anatomy.

- c. The intubation process may be visualized as the endotracheal tube is inserted.
- d. The tip of the Intubation Introducer Sheath may be deflected to aid in visualization and directing the endotracheal tube to its appropriate location.
- e. If anesthetic is required during the intubation process it may be delivered through the injection port located on the Introducer sheath.
- f. If visualization is difficult due to blood or mucus, injection of sterile water through the injection port will help in flushing the optics.
- g. At the end of the procedure remove the Intubation Endoscope and Sheath assembly from the endotracheal tube by gently pulling on the Introducer Sheath.
- h. Disconnect the Introducer Sheath from the Endoscope and discard in an appropriate container.

- i. The Endoscope may then be placed in its storage container for the next use.

*no  
must be  
cleaned*

3. MAINTENANCE AND STORAGE.

3-1 Intubation Endoscope

- a. If using a video system disconnect the Intubation Endoscope from the video camera.
- b. Place the Intubation Endoscope inside its storage container.

3-2 Introducer Sheath

The Introducer Sheath is a single patient use item and therefore requires no special handling or storage requirements.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

*118*

**APPENDIX E**

**PRODUCT DRAWINGS**

119  
000019





**APPENDIX F**

**PROPOSED ADVERTISING AND PROMOTIONAL COPY**

*122*  
000022

## DRAFT ADVERTISING BROCHURE

### Key Elements of Brochure

The Intubation Endoscope and Introducer Sheath for airway endoscopy management system offers:

- Outstanding fiberoptic image quality
- Articulating tip enhances steerability for accurate placement
- Malleable sheath adds flexibility for patient-specific anatomy
- Single-use, disposable sheath obviates resterilization between cases
- Modular design allows use under direct ocular vision or with video endoscopy equipment
- Self-contained, light weight system is mobile and easy to use
- Cost effective airway visualization

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

000023  
PB

## APPENDIX G

### COMPETITIVE MARKETING LITERATURE

In this Appendix are pieces of marketing literature, 510(k) Summaries of Safety and Effectiveness, or portions of 510(k)'s for the following products:

<u>APPENDIX</u>	<u>PREDICATE DEVICE</u>	<u>INFORMATION SUPPLIED</u>
G-1	SteBar Instrument Corp. Schroeder Oral/Nasal Directional Stylette™	Marketing Literature
G-2	Vision-Sciences EndoSheath®	510(k) Summary
G-3	American Optical Flexible Bronchoscope FBS-1	510(k), Applicable portions
G-4	Karl Storz Intubation Fiberscope	510(k) Summary

000024  
ph

**APPENDIX G-1**  
**COMPETITIVE MARKETING LITERATURE**

**SteBar Instr. Corp.**  
**Schroeder Oral/Nasal Stylette™**

PS

# Schroeder Oral/Nasal Directional Stylette™



*Provides absolute confidence and control by allowing the operator the ability to guide and direct the distal end of the endotracheal tube while intubating a patient.*



000026p/b

# Schroeder Oral/Nasal Directional Stylette™

With the Schroeder Oral/Nasal Directional Stylette™ crucial progress has been made. It enables the Anesthesiologist greater control over the tip movement and the ability to feel and sense the movement of the stylet while intubating a patient. This means the greatest possible safety for the patient.



Using the Schroeder Directional Stylette™, the tip of the endo-

tracheal tube can be guided safely and precisely into the trachea upon first insertion. This is possible due to a unique thumb button that provides the physician absolute control with one hand.

This pioneering solution further allows the operator to accurately place a tube nasally without the assistance of Magill forceps.

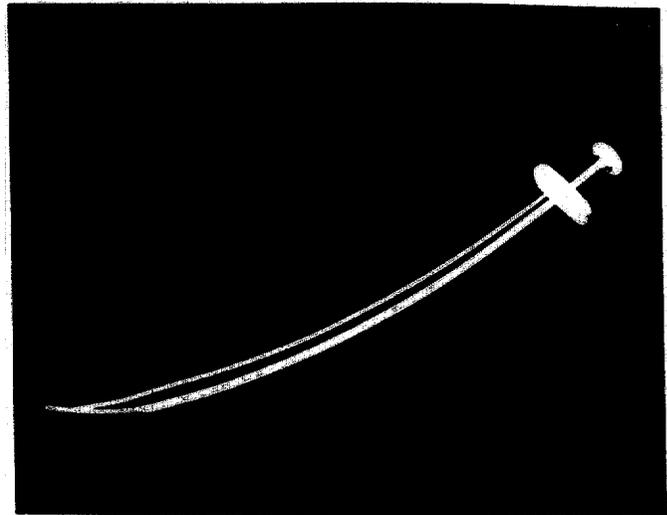
***The Schroeder Oral/Nasal Directional Stylette™ is truly the future of airway procurement and control.***

## SCHROEDER ORAL/NASAL DIRECTIONAL STYLETTE™

	Product No.	Description
Size 1	6570	Fits 6.5 - 7.0 mm ETT
Size 2	7580	Fits 7.5 - 8.0 mm ETT

Manufactured by **SteBar Instrument Corporation**  
Grand Rapids, Michigan  
1.800.968.0208

U.S. Patent # 5,299,871  
International Patents Pending  
For more information? Contact FDA/CDRH/OCE/DID at CDRH-FOI@fda.hhs.gov or 301-796-8114



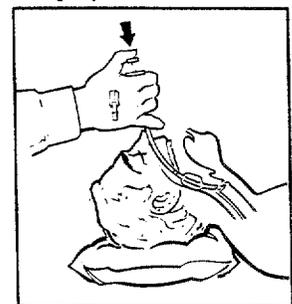
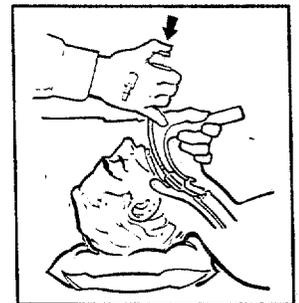
*"We have found the Schroeder Oral/Nasal Directional Stylette™ to be an effective and economical aid to intubation of the normal as well as the difficult airway. Its ease of directional control by both oral and nasal routes sets it apart from usual pre-formed intubation stylettes."*

**— Dr. J. Michael Watkins-Pitchford**  
*FRCAnaes, DA, MB BS, LRCP, MRCS*  
*Assistant Professor of Anesthesiology*  
*School of Medicine, Yale University*

*"The stylet functioned perfectly and what appeared to be a very difficult intubation suddenly became easy and very routine...I now need another stylet because the Chief of Anesthesia stole the one I had and has threatened to fire me if I took it back!"*

**— Richard D. McNary, MEd., CRNA, RRT**  
*Clinical Specialist, Battleboro Memorial Hospital*

- ◆ It's a "DIRECTIONAL" stylet
- ◆ Facilitates tube placement upon the first insertion
- ◆ Simple one-hand operation
- ◆ Quick accurate intubation
- ◆ Markedly reduced risk of injury
- ◆ Suitable for oral and nasal intubation
- ◆ Cost less than a traditional "wire" stylet



DISTRIBUTED BY:

000027

**APPENDIX G-2**  
**COMPETITIVE MARKETING LITERATURE**

**VISION-SCIENCES**

**EndoSheath®**

JUL - 2 1990

K961591

### Summary of Safety and Effectiveness

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Vision-Sciences is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." VSI chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

**Trade Name:** Endosheath® for use with the Vision-Sciences Model E-F100 Nasopharyngoscope

**Owner/Operator:** Vision-Sciences, Inc.  
6 Strathmore Rd.  
Natick, MA 01760

**Manufacturing Site:** Endosheath:  
Vision-Sciences, Inc.  
6 Strathmore Rd.  
Natick, MA 01760  
Reg. # 1223490

**Device Generic Name:** Nasopharyngoscope and accessories

**Classification:** According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (CFR 874.4760).

**Predicate Devices:**

EndoSheaths for use with the Machida Model ENT-4L, Olympus Model ENF Type 3P, Pentax Model FNL-10S and Pentax Model FNL-13S endoscopes (K921244, K925421, K933247)

Manufactured and Distributed by:  
Vision-Sciences, Inc.  
6 Strathmore Rd.  
Natick, MA 01760

**Product Description:**

The VSI EndoSheath for use with the VSI Model E-F100 Nasopharyngoscope consists of a sterile, disposable, protective sheath which covers the patient contact portion of the scope during a clinical procedure. The sheath is removed and disposed of following each procedure.

**Indications for Use:**

The EndoSheath provides a sterile, disposable protective covering for the scope to be used during endoscopic examination of the upper airway, vocal chords, and/or nasal passages.

00225  
129

000029

**Safety and Performance:**

The following in vitro functional tests were performed on the proposed Endosheath for use with the VSI Model E-F100 Nasopharyngoscope:

1. Functional and Burst Test
2. Scope Angulation (With and Without Sheath)
3. Scope OD (With and Without Sheath)
4. Sheath Longitudinal and Radial Strain when Loaded on Scope
5. Light Transmittance
6. Field of View
7. Scope Resolution (With and Without Sheath)

The following biocompatibility data was presented in support of this Premarket Notification:

1. Irritation
2. Sensitization
3. Cytotoxicity
4. Acute Systemic Toxicity
5. Hemolysis
6. Implantation

Microbial barrier testing using live polio virus as well as the Phi X 174 bacteriophage was also presented in support of the proposed label claims.

**Conclusion:**

Based on the indications for use, technological characteristics, and safety and performance testing, the EndoSheath for use with the VSI Model E-F100 Nasopharyngoscope has been shown to be safe and effective for its intended use.

00286

130

000030

**APPENDIX G-3**

**COMPETITIVE MARKETING LITERATURE**

**AMERICAN OPTICAL**

**Flexible Brochoscope  
FBS-1**

000031 (3)

MAY 13 1981

Mr. Albert P. Seprinski  
Director of Quality Assurance  
and Regulatory Affairs  
American Optical Corporation  
Scientific Instrument Division  
Southbridge, Massachusetts 01550

Ref: K811181  
Flexible Bronchoscope,  
Model FBS-1

Dear Mr. Seprinski:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to one marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either Class II (Standards) or Class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing devices, good manufacturing practices, labeling, and the misbranding and adulteration provisions of the Act. In the near future, the scope of general controls will be broadened to include additional regulations relating to restricted devices, records and reports, and others.

All regulations and information on meetings of the device classification panels, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire. Also, the Federal Register will notify you of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Office of the Hearing Clerk, FDA, 5600 Fishers Lane, Rockville, MD 20857.

This letter should not be construed as approval of your device or its labeling. If you desire advice on the status of labeling for your device or other information pertaining to your responsibilities under the Act, please contact the Bureau of Medical Devices, Division of Compliance Operations, 8757 Georgia Avenue, Silver Spring, MD 20910.

Sincerely yours,

*Robert S. Kennedy*

Robert S. Kennedy, Ph.D.  
Associate Director  
for Device Evaluation  
Bureau of Medical Devices

000032

**BEST AVAILABLE COPY**

B2

(Attachments "O", "P", "Q") can perform all of the functions of a laryngoscope, plus take biopsies of the respiratory tract. A suction by-pass control, separate from the biopsy port, permits suction to be used while the biopsy instrument is placed in the proper position for tissue sampling.

**B. SUBSTANTIAL EQUIVALENCY**

The American Optical Model FBS-1, Flexible Bronchoscope is substantially equivalent to the Olympus BF Type B2 (Olympus Optical Co., Ltd., Tokyo, Japan) which has been in commercial distribution within the United States at least two (2) years prior to May 28, 1976 date of enactment (Attachment "R", 2 pages). The following chart below provides comparison of characteristics between the American Optical and Olympus instruments:

<u>CHARACTERISTIC</u>	<u>AO</u>	<u>OLYMPUS</u>
Field of view	60°	75°
Direction of observation	Forward	Forward
Range of focus	5mm - ∞	3-50mm
Diameter of insertion tube	6.0mm	5.8mm
Diameter of distal end	6.0mm	5.2mm
Articulation	150° up, 120° down	130° up, 130° down
Working Length	600mm	605mm
Suction channel diameter	2.0mm	2.0mm

**BEST AVAILABLE COPY**

B3  
000033

## Care and Maintenance Reminders

The fiberscope is a delicate optical instrument to be carefully handled at all times. The image is transmitted through thousands of fragile glass fibers. These fibers will break under extreme flexing or bending and cause what appear to be minute black spots in the eyepiece where the image is viewed. Fiber breakage can be greatly reduced by proper handling.

**DO NOT BEND IN RADIUS OF LESS THAN 2".**

Do not deflect the end tip when tip is in a restricted or confined area. Heavy pressure can "snap" the fine gauge control wires.

Do not immerse the handle section with eyepiece in liquids of any type.

Do not attempt self-repair. Repair must be done by authorized personnel only.

### Preparation For Use

It is very important to become familiar with the flexible bronchoscope before using it in a difficult case. We recommend practice on an intubation model, find the anatomical landmarks and become accustomed to the view through the scope.

Connect the light guide - the continuous light guide is provided with fitting to connect to various type light sources, e.g., OLYMPUS CLB-4U. (ATTACHMENT "T")

Eyeiece Focusing - adjust the eyepiece to suit your own eyesight by rotating the focusing ring clockwise or counterclockwise until the image is in best focus.

Tip deflection - move the angle lever forward (toward tip) to bring the tip up and back (toward eyepiece) to bring the tip down. The handle can be rotated while the tip is deflected to view to the right or left.

Articulation Lock - to lock the distal end in any desired deflected angle push the locking lever forward.

Suction - connect a suction tube over the grip on the suction connector. Suction can be achieved by covering the hole at the top of the suction by pass valve.

To connect the by-pass valve to the bronchoscope insert the valve stem into the opening in the handle making sure to align the keyway. Engage the locking ring over the bayonet pins and turn counterclockwise to lock.

Biopsy Forceps - to use the biopsy insert the distal end of the forceps into the biopsy inlet and pass the forceps through the channel. The forceps should be inserted into the inlet and advanced using short strokes so the spring will not kink.

13h  
**BEST AVAILABLE COPY**

ATTACHMENT "D" (3 PAGES)

000034

- Do not deflect distal end by hand.
- Do not allow distal end to come into sharp contact with any hard objects.
- Do not force the brush or forceps through the channel if resistance is encountered.
- Do not immerse the control handle. Wipe with slightly damp cloth only.
- DO NOT STEAM STERILIZE THE BRONCHOSCOPE OR ANY OF THE ACCESSORIES.
- Do not attempt self repair. Repair must be done by authorized personnel only.

### Cleaning

The FBS should be cleaned immediately after use to prevent channel blockage.

1. Saturate a gauze pad with mild soap solution. Wipe the outer surface of the FBS with the pad and rinse the tube thoroughly with water.
2. Wet a gauze pad with 70% ethyl alcohol solution. Wipe the outer surface of the bronchoscope. Allow to dry.
3. If necessary clean the eyepiece or eyepiece lens and the distal tip lens with a cotton tip applicator moistened with alcohol solution.

### Cleaning the channel

1. Aspirate cleaning solution through the channel with the distal tip immersed in the solution. To aspirate cover the hole on the top of the valve.
2. Insert the cleaning brush into the biopsy inlet and through the entire length of the channel.
3. Again aspirate by immersing the distal end in cleaning solution.
4. Aspirate the channel using water.
5. Channel must be immediately and completely suction dried.
6. The inlet valve system should be removed, disassembled and cleaned in a disinfection solution. *↑ need different name*

### Disinfection

After cleaning the bronchoscope and the internal channels as described in the cleaning sections, repeat the same procedure using disinfecting solution where cleaning solution is specified and sterile water where clean water is specified.

135  
BEST AVAILABLE COPY  
000035

Clean the distal end lens with a cotton tip applicator moistened with 70% alcohol solution.

Sterilization

*scope & accessories*

The scope should be sterilized in ethylene oxide after each use following the sterilizing equipment manufacturer's procedures. The scope must be clean and dry before sterilizing. Do not exceed 130°F or 10 lb. per square inch.

DO NOT IMMERSE (the handle is not watertight).

DO NOT STEAM STERILIZE (extreme heat will damage the fibers).

Storage

The FBS and accessories should be stored with flexible tube straight in a clean dry area such as a closed cabinet.

The FBS and accessories should never be stored in the carrying case. They should be resterilized before use if transported in the carrying case. The carrying case is not a sterile environment.

Information Parts and Repair

American Optical Corporation  
Instrument Division  
Fiber Optics  
Southbridge, Massachusetts 01550  
17-765-9711

**BEST AVAILABLE COPY**

*136*

000036

**APPENDIX G-4**  
**COMPETITIVE MARKETING LITERATURE**

**Karl Storz**  
**Intubation Fiberscope**

137  
000037



Karl Storz  
Endoscopy-America, Inc.

600 Corporate Pointe  
Culver City, California 90230-7600  
Phone 310 558 1500

Toll Free 800 421 0837  
Fax 310 410 5527

2961178

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**MAY 14 1986**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document are accurate and complete to the best of KSEA's knowledge.

**Applicant:** Karl Storz Endoscopy - America, Inc.  
600 Corporate Pointe  
Culver City, CA 90230  
(310) 558-1500

**Contact:** Betty M. Johnson  
Manager, Regulatory Affairs

**Device Identification:** Common Name  
Fiberscope  
Trade Name  
Karl Storz intubation fiberscope

**Indication:** The Karl Storz intubation fiberscope is designed to provide visual access to the larynx and tracheobronchial tree during ENT endoscopic procedures.

**Device Description:** The Karl Storz intubation fiberscope consists of a focusing ocular lens, a moveable eyepiece, a rigid curved stainless steel shaft that houses the fiber optic imaging and illumination system, a distal objective lens, a channel for insufflation of oxygen, a sliding cap to accommodate endotracheal catheters of various sizes and a connection for a fiber optic light cable.

**Substantial Equivalence:** The Karl Storz intubation fiberscope is substantially equivalent to the predicate devices since the basic features, design and intended uses are the same or similar. The minor differences in dimensions between the Karl Storz intubation fiberscope and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed: Betty M. Johnson  
Betty M. Johnson  
Manager, Regulatory Affairs

138

000038

## APPENDIX H

### Substantial Equivalence

The Urohealth Systems, Inc. Intubation Endoscope and Introducer Sheath is substantially equivalent to the predicate devices cited in Table 1. below because the basic design and features of the bronchoscope are nearly identical to one or more of the cited devices.

The malleable portion of the introducer sheath is not used in the other devices but does not introduce any significant new elements of design in the materials or operational principles that could affect the safety or effectiveness of the device. Functional performance testing of the sheath will be performed to verify maintenance of the sterile barrier under normal usage conditions. This testing is described below.

The deflecting tip is quite similar to the Schroeder Oral/Nasal Directional Stylette™ and is equivalent to American Optical Flexible Bronchoscope, FBS-1.

All materials that have patient contact have been or will be tested for biocompatibility in accordance with EN 30993. The materials that have such contact are listed in Appendix K.

### CONCLUSION

Based on the indications for use, technological characteristics, and safety and performance testing, the Intubation Endoscope and Introducer Sheath have been shown to be safe and effective for its intended use.

139  
000039

**APPENDIX I**

**COMPARISON OF SIMILARITIES AND DIFFERENCES**

120  
000040

APPENDIX I

COMPARISON OF SIMILARITIES AND DIFFERENCES

MFR/SCOPE	SteBar Instr. Corp.	VISION-SCIENCES	AMERICAN OPTICAL	Karl Storz	UROHEALTH
Feature	Schroeder Oral/Nasal Stylette™	EndoSheath®	Flexible Brochoscope FBS-1	Intubation Fiberscope	Intubation Endoscope and Introducer Sheath
510(k) No.	not known	K961591	K811181	K961178	TBD
Statement of Intended use	Enables endotracheal tube to be guided safely and precisely into the trachea upon first insertion.	EndoSheath provides a sterile, disposable protective covering for the scope to be used during endoscopic examination of the upper airway, vocal chords, and/or nasal passages.	Flexible laryngoscope provides a direct illuminated view of the pharynx, larynx, trachea and bronchi. Can be used for difficult intubations.	Provides visual access to the larynx and tracheobronchi al tree during ENT endoscopic procedures.	Used for direct visualization in the trachea and lungs during fiberoptically assisted intubation and airway management.
Device Description	Not fully described in marketing literature.	EndoSheath consists of a sterile, disposable, protective sheath	Eyepiece focus, finger-tip control knob for end-tip movement, Remote controlled movable	Fiberscope consists of a focusing ocular lens, a moveable	Endoscope consists of a focusing ocular lens, a distal objective lens, and a connection for a fiber

000041

MFR/SCOPE	SteBar Instr. Corp.	VISION-SCIENCES	AMERICAN OPTICAL	Karl Storz	UROHEALTH
Feature	Schroeder Oral/Nasal Stylette™	EndoSheath® which covers the patient contact portion of the scope during a clinical procedure. The sheath is removed and disposed of following each procedure.	Flexible Brochoscope FBS-1 end-tip for precise placement while viewing internal anatomy.	Intubation Fiberscope eyepiece, a rigid curved stainless steel shaft that houses the fiber optic imaging and illumination system, a distal objective window, a channel for insufflation of oxygen, a sliding cap to accommodate endotracheal catheters of various sizes.	Intubation Endoscope and Introducer Sheath optic light cable. The introducer sheath consists of a flush channel, scope insertion channel, a deflecting mechanism for the distal tip, and a distal window.
Field of View	n/a	n/a	60°	not known	≥ 70°

172

000042

MFR/SCOPE	SteBar Instr. Corp.	VISION-SCIENCES	AMERICAN OPTICAL	Karl Storz	UROHEALTH
<b>Feature</b>  <b>INTRODUCER SHEATH</b> Overall Length Working Length	Schroeder Oral/Nasal Stylette™  not known not known	EndoSheath®  Not describe in 510(k) Summary	Flexible Bronchoscope FBS-1  670mm 600mm	Intubation Fiberscope  not known not known	Intubation Endoscope and Introducer Sheath  1450mm 510mm
How Supplied	not known	Supplied sterile and single use, disposable	Bronchoscope is reusable with ethylene oxide sterilization	not known	Fiberoptics are reusable with ethylene oxide sterilization and provided nonsterile. Introducer sheath is single use disposable, supplied sterile.
Tip Deflection	Uni-directional	n/a	Up 150° Down 120°	Not stated in 510(k) Summary	Up 90°
Deflection Method	Proximal thumb button activates the deflection of the distal tip.	n/a	Manipulation at the proximal end activates deflection of the distal tip.	Not stated in 510(k) Summary	Manipulation at the proximal end activates the deflection of the distal tip.

123

MFR/SCOPE	SteBar Instr. Corp.	VISION-SCIENCES	AMERICAN OPTICAL	Karl Storz	UROHEALTH
Feature	Schroeder Oral/Nasal Stylette™	EndoSheath®	Flexible Brochoscope FBS-1	Intubation Fiberscope	Intubation Endoscope and Introducer Sheath
Distal Diameter	unknown	Not described in 510(k) Summary	6.0mm	Not stated in 510(k) Summary	3.4mm
Instrument or Flushing Channel	unknown	Not described in 510(k) Summary	2.0mm	Not stated in 510(k) Summary	<2.5mm Connector: standard luer lock
Malleable Sheath	none	none	none	none	Easily shaped and maintains shape during the intubation procedure.
Biocompatibility	unknown	Stated as biocompatible in 510(k) Summary	Stated as biocompatible in 510(k)	Not stated in 510(k) Summary	All components that have body contact have been or will be tested and determined to be biocompatible in accordance with EN 30993.

2hh

## APPENDIX J

### PATIENT CONTACTING COMPONENTS AND MATERIALS

#### INTRODUCER SHEATH

##### COMPONENT

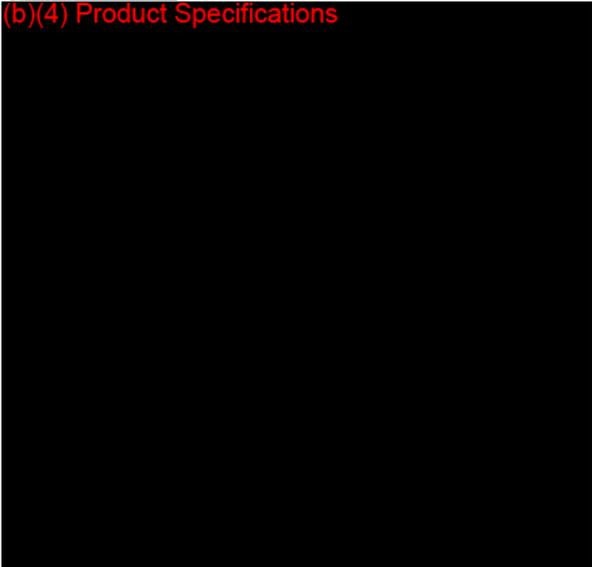
Bonding Material

Distal Tip  
Pull Tube  
Handle Housing  
Female Luer  
Distal Window

Lumen Body Tubing  
Malleable Wire  
Scope Tubing  
Thumb Lever

##### MATERIAL

(b)(4) Product Specifications



#### BIOCOMPATIBILITY

Biocompatibility testing will be conducted on both component level and finished devices (sterile, if applicable). This testing will include but is not limited to cytotoxicity, sensitization, and irritation. This device is considered Body Contact surface of Mucosal membranes for a limited contact duration (less than 24 hours). This testing is in accordance with EN 30993 for medical devices.

#### FIBEROPTIC SCOPE AND COUPLER

There are no patient contacting components in the fiberoptic scope.

## APPENDIX K

### PERFORMANCE TESTING, STERILIZATION, AND PACKAGING

#### FUNCTIONAL PERFORMANCE TESTING

The malleable sheath will be tested to ensure the sterile barrier is maintained during the entire procedure under normal usage conditions. Validation of all bonded joints will be performed per ASTM F1147-88.

#### STERILIZATION

Both Gamma sterilization and EtO sterilization may be utilized. Validation will be accomplished per ANSI/AAMI/ISO guidelines for medical products. An overkill approach will be completed at an SAL of  $10^{-6}$ .

If EtO sterilization is used the product will be tested per USP guidelines for residual levels of Ethylene Oxide, Ethylene Chlorohydrin, and Ethylene Glycol for product contacting mucosal membranes.

#### PACKAGING

The sterile single use package will be a Tyvek to PET/LDPE laminated pouch sealed by conventional methods. The pouches will be placed in a primary chipboard box (5 to 10 units per box). These units will then be placed in a corrugated shipper.

**APPENDIX L**

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

INT

000047

### 510(k) SUMMARY

In accordance with the requirements of SMDA 1990 and 21 CFR 807.92 this 510(k) Summary of Safety and Effectiveness is submitted with the Premarket Submission.

Company Name: UROHEALTH Systems, Inc.  
3050 Redhill Ave.  
Costa Mesa, CA 92626

Contact Person: Ronald Bergeson  
Telephone Number: 714.708.7748, ext. 248

Device Name: Bronchoscope

Proprietary Device Name: Intubation Endoscope and  
Introducer Sheath

Classification Name: Bronchoscope (flexible or rigid) and  
accessories

Predicate Devices: SteBar Instr. Corp. Schroeder Oral/Nasal  
Stylette™

Vision-Sciences EndoSheath®

AMERICAN OPTICAL Flexible  
Brochoscope FBS-1

Karl Storz Intubation Fiberscope

Device Description: UROHEALTH Intubation Endoscope Introducer  
Sheath is a device that consists a malleable or  
nonmalleable introducer sheath that houses a  
channel for insufflation of oxygen or fluid  
delivery, a deflecting mechanism for the distal  
tip, a channel for scope insertion, and a distal  
window. The reusable fiber optic imaging and  
illumination system consists of a focusing  
ocular lens, a distal objective lens, and a  
connection for a fiber optic light cable.

128  
000048

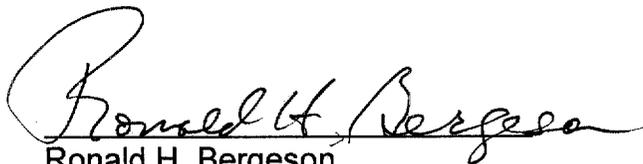
- Intended Use:** The Intubation Endoscope and Introducer Sheath are used in the direct visualization in the trachea and lungs during fiberoptically assisted intubation and airway management.
- Performance Testing:** The Intubation Endoscope and Introducer Sheath will be tested to ensure integrity of the sterile barrier under normal usage conditions. All bonded joints will be tested according to the appropriate ASTM procedure.
- Biocompatibility:** Biocompatibility testing will be conducted on both component level and finished devices (sterile, if applicable). This testing will include but is not limited to cytotoxicity, sensitization, and irritation. The device is considered body contact surface of mucosal membranes for a limited (less than 24 hours) contact duration. This testing is in accordance with EN 30993 for medical devices.
- Substantial Equivalence:** Based on the indications for use, technological characteristics, and safety and performance testing to be completed, the UROHEALTH Intubation Endoscope and Introducer Sheath will be shown to be safe and effective for its intended use.

119  
000049

**APPENDIX M**

**TRUTHFUL AND ACCURATE STATEMENT**

As a responsible management representative of UROHEALTH Systems, Inc. I believe that, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate, and that no material fact has been omitted.



Ronald H. Bergeson  
Corporate Director, Regulatory Affairs  
UROHEALTH Systems, Inc.

1/10/97  
DATE

150

000050