

510(k) Summary of Safety and Effectiveness
Clear-Vu System
Minimally Invasive Devices, LLC

NOV - 6 2008

510(k) Submitter	Minimally Invasive Devices, LLC 1275 Kinnear Road Columbus, Ohio 43212
Contact Person	Wayne L. Poll, MD, Chairman <i>Phone:</i> (614) 580-2022 <i>Fax:</i> (614) 889-7630 <i>E-mail:</i> waynepoll@hotmail.com
Date Prepared	Revised October 28, 2008
Device Name	<i>Proprietary Name:</i> Clear-Vu System <i>Common Name:</i> endoscope lens cleaning and defogging device <i>Classification Name:</i> "accessory, endoscope," a class II device in accordance with 21 CFR § 876.1500
Intended Use	The Clear-Vu System is a single-use, disposable laparoscopic accessory device intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site.
Device Description	The Clear-Vu System consists of a multi-lumen sheath assembly mounted on the shaft of the laparoscope, which connects to the existing CO ₂ insufflation circuit to defog the laparoscope lens and divert surgical debris, and connects to the existing surgical irrigation system to clean the lens via saline flush.
Substantial Equivalence	The Clear-Vu System is substantially equivalent in terms of safety and effectiveness to the following predicate devices: <ol style="list-style-type: none">1. Defogging Heated Endoscopic Lens Protector / K062779 New Wave Surgical Corp.2. Endo-Scrub® 2 / K982594 Xomed, Inc.3. SeeClear™ Laparoscopic Smoke Evacuation System/510(k) Exempt JLJ Medical Devices International, LLC
Technological Comparison	The Clear-Vu System is substantially equivalent to the cited predicate devices in terms of intended use, and the technological differences are not significant relative to the safety or effectiveness of the new device.
Performance Testing-Bench	The device was subjected to simulated use testing to demonstrate its effectiveness in a surgical environment simulation chamber.
Performance Testing-Animal	The device was subjected to preclinical animal testing to demonstrate its effectiveness in a porcine model.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Minimally Invasive Devices, LLC
% Mr. Michael H. Southworth, RAC
Principal & Senior Consultant
Southworth & Associates, LLC
1035 Waldo Way
TWINSBURG OH 44087

NOV - 6 2008

Re: K080613
Trade/Device Name: Clear-Vu™ System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG and GCJ
Dated: October 28, 2008
Received: October 30, 2008

Dear Mr. Southworth:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

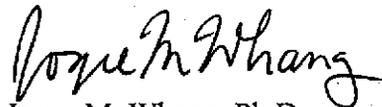
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K080613

Device Name: Clear Vu System

Indications for Use: Clear-Vu is a single-use, disposable laparoscopic accessory device that is intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site.

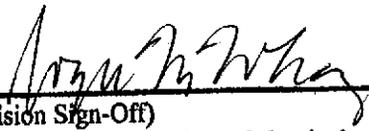
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080613



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Minimally Invasive Devices, LLC
% Mr. Michael H. Southworth, RAC
Principal & Senior Consultant
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1035 Waldo Way
TWINSBURG OH 44087

NOV - 6 2008

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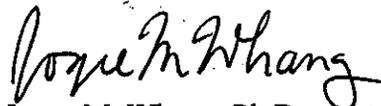
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Sincerely yours,



Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K080613

Device Name: Clear Vu System

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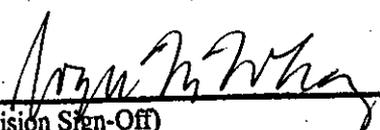
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K080613



October 30, 2008

MINIMALLY INVASIVE DEVICES LLC
C/O SOUTHWORTH & ASSOCIATES, LLC
1035 WALDO WAY
TWINSBURG, OHIO 44087
UNITED STATES
ATTN: MICHAEL H. SOUTHWORTH

510k Number: K080613

Product: CLEAR-VU SYSTEM, MODELS: CVL-0

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. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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



October 02, 2008

MINIMALLY INVASIVE DEVICES LLC
C/O SOUTHWORTH & ASSOCIATES, LLC
1035 WALDO WAY
TWINSBURG, OHIO 44087
UNITED STATES
ATTN: MICHAEL H. SOUTHWORTH

510k Number: K080613
Product: CLEAR-VU SYSTEM, MOD
Extended Until: 03/03/2009

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 (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

Southworth & Associates

Medical Device Regulatory Affairs & Compliance

October 1, 2008

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

Attn: *510(k) Document Mail Center*

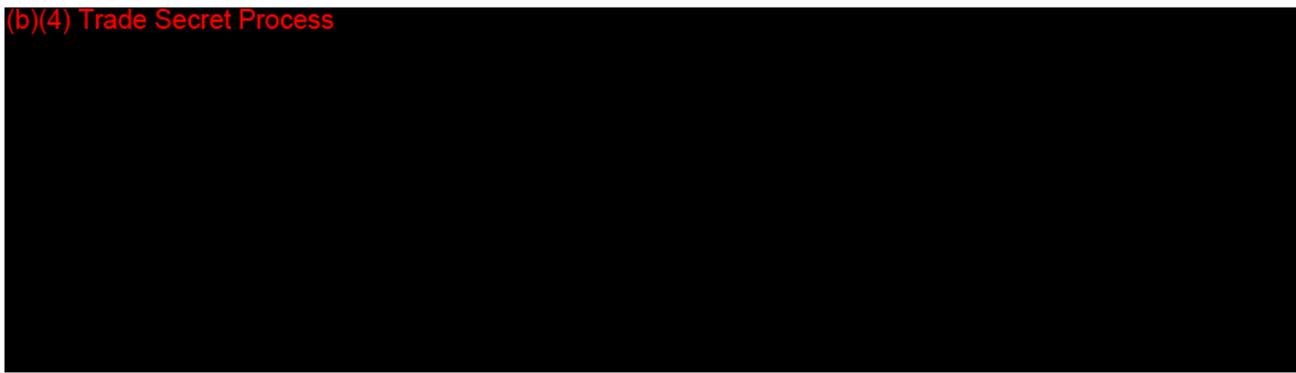
Re: *K080613*
Clear-Vu System™
Minimally Invasive Devices, LLC

FDA CDRH DMC

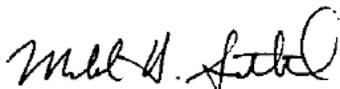
OCT 2 2008

Received

(b)(4) Trade Secret Process



Sincerely,



Michael H. Southworth, RAC
Principal & Senior Consultant

Confidential

K28

April 30, 2008

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

MINIMALLY INVASIVE DEVICES LLC
C/O SOUTHWORTH & ASSOCIATES, LLC
1035 WALDO WAY
TWINSBURG, OH 44087
ATTN: MICHAEL H. SOUTHWORTH

510(k) Number: K080613
Product: CLEAR-VU SYSTEM,
MODELS:
CVL-01-1000,
CVL-01-1030,

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. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

If after 30 days the additional information (AI), 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 (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. 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 questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

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

March 05, 2008

MINIMALLY INVASIVE DEVICES LLC
C/O SOUTHWORTH & ASSOCIATES, LLC
1035 WALDO WAY
TWINSBURG, OH 44087
ATTN: MICHAEL H. SOUTHWORTH

510(k) Number: K080613
Received: 04-MAR-2008
Product: CLEAR-VU SYSTEM,
MODELS: CVL-01-1000,
CVL-01-1030,
CVL-01-1045

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (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 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/mdufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

A new provision of the Food and Drug Administration Amendments Act of 2007, 42 U.S.C. 282(j)(5)(B), requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany all 510(k)/HDE/PMA submissions on or after December 26, 2007. You are responsible for registering certain device clinical trials in the Clinical Trials Data Bank (<http://prsinfo.clinicaltrials.gov>). If your submission does not include FDA Form 3674, please send 2 hardcopies of the completed certification form referencing the submission number identified above. Additional information about the new certification

form may be found at the following link to the Federal Register Notice (<http://www.fda.gov/OHRMS/DOCKETS/98fr/07-6023.htm>).

Please note the following documents as they relate to 510(k) review:

- 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process.
- 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/electsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240) 276-4040.

Sincerely yours,

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

K080613

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Traditional 510(k) Notification Clear-Vu System Minimally Invasive Devices, LLC

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13

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade Write the Payment Identification number on your check.	
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:			
<ol style="list-style-type: none"> 1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer. 6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center. 			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)		2. CONTACT NAME	
MINIMALLY INVASIVE DEVICES LLC 1275 KINNEAR ROAD Columbus OH 43212 US		William Post	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)		2.1 E-MAIL ADDRESS wpost1@columbus.rr.com	
		2.2 TELEPHONE NUMBER (include Area code) 614-4487675	
		2.3 FACSIMILE (FAX) NUMBER (Include Area code) 614-2688103	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dcl/mdufma)			
Select an application type:		3.1 Select one of the types below	
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party		<input checked="" type="checkbox"/> Original Application	
<input type="checkbox"/> 513(g) Request for Information		Supplement Types:	
<input type="checkbox"/> Biologics License Application (BLA)		<input type="checkbox"/> Efficacy (BLA)	
<input type="checkbox"/> Premarket Approval Application (PMA)		<input type="checkbox"/> Panel Track (PMA, PMR, PDP)	
<input type="checkbox"/> Modular PMA		<input type="checkbox"/> Real-Time (PMA, PMR, PDP)	
<input type="checkbox"/> Product Development Protocol (PDP)		<input type="checkbox"/> 180-day (PMA, PMR, PDP)	
<input type="checkbox"/> Premarket Report (PMR)			
<input type="checkbox"/> Annual Fee for Periodic Reporting (APR)			
<input type="checkbox"/> 30-Day Notice			
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)			
<input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA		<input checked="" type="checkbox"/> NO, I am not a small business	
4.1 If Yes, please enter your Small Business Decision Number:			
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.			
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population	
<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)			
<input type="checkbox"/> YES		<input checked="" type="checkbox"/> NO	
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION			
(b)(4) Trade		12-Feb-2008	

https://fdasfinapp8.fda.gov/OA_HTML/mdufmaCScdCfItemsPopup.jsp?vname=Willia... 2/12/2008

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission: March 1, 2008
User Fee Payment ID Number: (b)(4) Trade Secret
FDA Submission Document Number (if known): N/A

SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Minimally Invasive Devices, LLC		Establishment Registration Number (if known) N/A	
Division Name (if applicable) N/A		Phone Number (including area code) (614) 580-2022	
Street Address 1275 Kinnear Road		FAX Number (including area code) (614) 889-7630	
City Columbus	State / Province Ohio	ZIP/Postal Code 43212	Country USA
Contact Name Wayne L. Poll, MD			
Contact Title Chairman		Contact E-mail Address wpost@midsurgical.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name Southworth & Associates, LLC			
Division Name (if applicable) N/A		Phone Number (including area code) (216) 287-0312	
Street Address 1035 Waldo Way		FAX Number (including area code) (330) 425-2147	
City Twinsburg	State / Province Ohio	ZIP/Postal Code 44087	Country USA
Contact Name Michael H. Southworth, RAC			
Contact Title Principal & Senior Consultant		Contact E-mail Address sa_consulting@hotmail.com	

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

- Withdrawal
- Additional or Expanded Indications
- Request for Extension
- Post-approval Study Protocol
- Request for Applicant Hold
- Request for Removal of Applicant Hold
- Request to Remove or Add Manufacturing Site

- Change in design, component, or specification:
 - Software / Hardware
 - Color Additive
 - Material
 - Specifications
 - Other (specify below)

- Location change:
 - Manufacturer
 - Sterilizer
 - Packager

- Process change:
 - Manufacturing
 - Sterilization
 - Packaging
 - Other (specify below)

- Labeling change:
 - Indications
 - Instructions
 - Performance
 - Shelf Life
 - Trade Name
 - Other (specify below)

- Report Submission:
 - Annual or Periodic
 - Post-approval Study
 - Adverse Reaction
 - Device Defect
 - Amendment

- Response to FDA correspondence:

- Change in Ownership
- Change in Correspondent
- Change of Applicant Address

- Other Reason (specify):

SECTION D2

REASON FOR APPLICATION - IDE

- New Device
- New Indication
- Addition of Institution
- Expansion / Extension of Study
- IRB Certification
- Termination of Study
- Withdrawal of Application
- Unanticipated Adverse Effect
- Notification of Emergency Use
- Compassionate Use Request
- Treatment IDE
- Continued Access

- Change in:
 - Correspondent / Applicant
 - Design / Device
 - Informed Consent
 - Manufacturer
 - Manufacturing Process
 - Protocol - Feasibility
 - Protocol - Other
 - Sponsor

- Reponse to FDA Letter Concerning:
 - Conditional Approval
 - Deemed Approved
 - Deficient Final Report
 - Deficient Progress Report
 - Deficient Investigator Report
 - Disapproval
 - Request Extension of Time to Respond to FDA
 - Request Meeting
 - Request Hearing

- Report submission:
 - Current Investigator
 - Annual Progress Report
 - Site Waiver Report
 - Final

- Other Reason (specify):

SECTION D3

REASON FOR SUBMISSION - 510(k)

- New Device

- Additional or Expanded Indications

- Change in Technology

- Other Reason (specify):

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	KOG	2	GCJ	3	
5		6		7	
				<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	

Information on devices to which substantial equivalence is claimed (if known)		
510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K062779	Defogging Heated Endoscopic Lens Protector (D.H.E.L.P.) New Wave Surgical Corporation
2	K982594	Endo-Scrub® 2 Xomed, Inc.
3	N/A – 510(k) Exempt	SeeClear™ Laparoscopic Smoke Evacuation System JLJ Medical Devices Int'l, LLC
4		
5		
6		

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
endoscope lens cleaning and defogging device

Trade or Proprietary or Model Name for This Device	Model Numbers
1 Clear-Vu System, 10mm/0° tip laparoscopes	1 CVL-01-1000
2 Clear-Vu System, 10mm/30° tip laparoscopes	2 CVL-01-1030
3 Clear-Vu System, 10mm/45° tip laparoscopes	3 CVL-01-1045
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome)					
1	2	3	4	5	6
C070324					
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code KOG	C.F.R. Section (if applicable) 21 CFR § 876.1500	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Gastroenterology and Urology Devices Panel (76)		

Indications (from labeling)
 Clear-Vu is a single-use, disposable laparoscopic accessory device that is intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site.

53 5

Note: Submission of this information does not effect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

Original
 Add Delete

FDA Establishment Registration Number
TBD

Manufacturer Contract Sterilizer
 Contract Manufacturer Repackager / Relabeler

Company / Institution Name
TBD

Establishment Registration Number

Division Name (if applicable)

Phone Number (including area code)
()

Street Address

FAX Number (including area code)
()

City

State / Province

ZIP/Postal Code

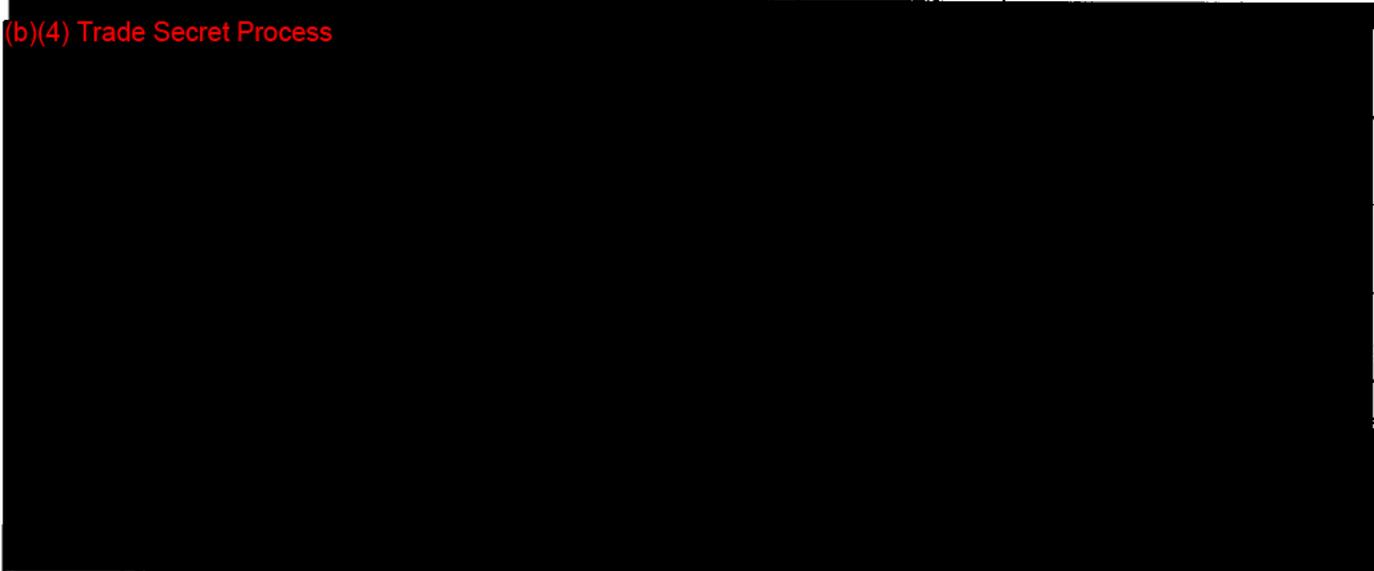
Country

Contact Name

Contact Title

Contact E-mail Address

(b)(4) Trade Secret Process



Original
 Add Delete

FDA Establishment Registration Number

Manufacturer Contract Sterilizer
 Contract Manufacturer Repackager / Relabeler

Company / Institution Name

Establishment Registration Number

Division Name (if applicable)

Phone Number (including area code)
()

Street Address

FAX Number (including area code)
()

City

State / Province

ZIP/Postal Code

Country

Contact Name

Contact Title

Contact E-mail Address

SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ANSI/AAMI/ ISO 11137- 1:2006	International Organization for Standardization	Sterilization of health care products – Radiation-- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2006	2006
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: K080613

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.	SECTION 4	
Table of Contents.	PAGE 1	
Truthful and Accurate Statement.	SECTION 7	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	SECTION 4	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	SECTION 4	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.	SECTION 10	
Statement of Indications for Use that is on a separate page in the premarket submission.	SECTION 5	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.	SECTION 13	
510(k) Summary or 510(k) Statement.	SECTION 6	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	SECTION 9	
Identification of legally marketed predicate device. *	SECTION 13	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	N/A	
Class III Certification and Summary. **	N/A	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	N/A	
510(k) Kit Certification ***	N/A	

- * - May not be applicable for Special 510(k)s.
- ** - Required for Class III devices, only.
- *** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission: N/A

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission: N/A

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which		

is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

- * - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	SECTION 12	
b) Sterilization and expiration dating information:	SECTION 11	
i) sterilization process	SECTION 11	
ii) validation method of sterilization process	SECTION 11	
iii) SAL	SECTION 11	
iv) packaging	SECTION 11	
v) specify pyrogen free	N/A	
vi) ETO residues	N/A	
vii) radiation dose	SECTION 11	
viii) Traditional Method or Non-Traditional Method	SECTION 11	
c) Software Documentation:	N/A	

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ____ Yes ____ No

Reviewer: _____

Concurrence by Review Branch: _____

Date: _____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>



CONFIDENTIAL

February 25, 2008

FDA CDRH DMC

MAR - 4 2008

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

Received

Attn: 510(k) Document Mail Center

**Re: Traditional 510(k) Notification
Clear-Vu™ System
Minimally Invasive Devices, LLC**

Pursuant to the requirements of section 510(k) of the Federal Food, Drug, and Cosmetic Act, as amended, and 21 CFR Part 807 Subpart E, the purpose of this letter, submitted here in triplicate, is to notify FDA that Minimally Invasive Devices LLC (MID) intends to introduce into commercial distribution a new medical device, the Clear-Vu System.

Clear-Vu is a single-use, disposable laparoscopic accessory device that is intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site.

MID submitted a 513(g) Request to FDA (C070324) to obtain a written statement from the Agency respecting the device classification and premarket regulatory controls applicable to our device. In response to our 513(g) Request, FDA confirmed the Clear-Vu System is an endoscope accessory in accordance with 21 CFR § 876.1500(b)(1), which is a Class II medical device subject to the general controls of the FD&C Act, including 510(k) notification.

Confidential

510(k) Notification Submitter

Minimally Invasive Devices, LLC
1275 Kinnear Road
Columbus, Ohio 43212
Contact Person: Wayne L. Poll, MD, Chairman
Phone: (614) 580-2022
Fax: (614) 268-8103
E-mail: waynepoll@hotmail.com

510(k) Notification Type

This is a Traditional 510(k) Notification.

Device Names

Common Name: endoscope lens cleaning and defogging device
Classification Name: accessory, endoscope
Proprietary Name: Clear-Vu System

Classification Regulation

An endoscope accessory is a class II medical device in accordance with device classification regulation 21 CFR § 876.1500(b)(1).

Product Code

The applicable FDA product codes are KOG (endoscope and/or accessory) and GCJ (laparoscope, general and plastic surgery).

Classification Panel

The device classification panel is the Gastroenterology and Urology Devices Panel (76).

Special Controls:

No special controls have been established for endoscope accessories under § 876.1500.

Device Manufacturing Site / FDA Establishment Registration:

MID will not manufacture the Clear-Vu System. The device will be manufactured by a qualified contract device manufacturing establishment (to be determined). In accordance with the requirements of 21 CFR Part 807, Subpart B, MID will register its establishment with FDA as a Specification Developer within 30 days of commencement of device manufacture.

Prior FDA Correspondence

As indicated above, MID submitted a 513(g) Request to FDA (C070324) to obtain a written statement from the Agency respecting the device classification and premarket regulatory controls applicable to our device. Section 14 of this 510(k) Notification includes a copy of the MID's October 8, 2007 513(g) Request and FDA's November 30, 2007 513(g) response.

Design and Use of the Device

Question	Yes	No
<i>Is the device intended for prescription use (21 CFR Part 801, Subpart D)?</i>	X	
<i>Is the device intended for over-the-counter use (21 CFR Part 807, Subpart C)?</i>		X
<i>Does the device contain components derived from a tissue or other biologic source?</i>		X
<i>Is the device provided sterile?</i>	X	
<i>Is the device intended for single use?</i>	X	
<i>Is the device a reprocessed single use device?</i>		X
<i>Does the device contain a drug?</i>		X
<i>Does the device contain a biologic?</i>		X
<i>Does the device use software?</i>		X
<i>Does the submission include clinical information?</i>		X
<i>Is the device implanted?</i>		X

510(k) Submission Content

This 510(k) Notification has been prepared in accordance with FDA's "Format for Traditional and Abbreviated 510(k)s" guidance document and contains all applicable information (see Table of Contents). The elements of the FDA guidance which ***do not apply*** are as follows:

- **Class III Summary and Certification.** An endoscope accessory is not a preamendments class III device.
- **Financial Certification or Disclosure Statement.** This 510(k) Notification does not rely on or contain the results of any clinical studies and the requirements of 21 CFR Part 54 do not apply.
- **Declarations of Conformity and Summary Reports.** This is a Traditional 510(k) Notification, not an Abbreviated 510(k) Notification.
- **Software.** The Clear-Vu System does not include software or firmware.
- **Electromagnetic Compatibility and Electrical Safety.** The Clear-Vu System is a passive device and raises no electromagnetic compatibility or electrical safety concerns.
- **Performance Testing – Bench.** No bench performance testing is necessary to demonstrate the substantial equivalence of the Clear-Vu System.
- **Performance Testing – Animal.** No preclinical/animal performance testing is necessary to demonstrate the substantial equivalence of the Clear-Vu System.
- **Performance Testing – Clinical.** No clinical performance testing is required to demonstrate the substantial equivalence of the Clear-Vu System.

Confidentiality Request

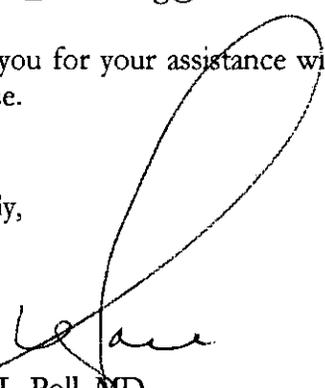
This 510(k) Notification comprises trade secrets and other information that is confidential and privileged under 21 CFR § 20.61(a) and (b), and we request that FDA not make any information in this submission publicly available after substantial equivalence order issuance beyond that granted under the disclosure provisions of 21 CFR § 20.61.

We believe this 510(k) Notification contains sufficient information to allow FDA to reach a substantial equivalence determination. If you have any questions or require any additional information, please contact our FDA regulatory consultant who is authorized to represent Minimally Invasive Devices, LLC to FDA with respect to this 510(k) Notification:

Michael H. Southworth, RAC
Southworth & Associates, LLC
(216)287-0312 (phone)
(330)425-2147 (fax)
sa_consulting@hotmail.com (e-mail).

Thank you for your assistance with this matter. We look forward to your earliest possible response.

Sincerely,



Wayne L. Poll, MD
Chairman

cc: Michael H. Southworth, RAC
Southworth & Associates, LLC

510(k) Enclosures

Indications for Use Statement

510(k) Number: K080613

Device Name: Clear Vu System

Indications for Use: Clear-Vu is a single-use, disposable laparoscopic accessory device that is intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary of Safety and Effectiveness

Clear-Vu System Minimally Invasive Devices, LLC

510(k) Submitter Minimally Invasive Devices, LLC
1275 Kinnear Road
Columbus, Ohio 43212

Contact Person Wayne L. Poll, MD, Chairman
Phone: (614) 580-2022
Fax: (614) 889-7630
E-mail: waynepoll@hotmail.com

Date Prepared February 25, 2008

Device Name *Proprietary Name:* Clear-Vu System
Common Name: endoscope lens cleaning and defogging device
Classification Name: "accessory, endoscope," a class II device in accordance with 21 CFR § 876.1500

Intended Use The Clear-Vu System is a single-use, disposable laparoscopic accessory device intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site.

Device Description The Clear-Vu System consists of a multi-lumen sheath assembly mounted on the shaft of the laparoscope, which connects to the existing CO₂ insufflation circuit to defog the laparoscope lens and divert surgical debris, and connects to the existing surgical irrigation system to clean the lens via saline flush.

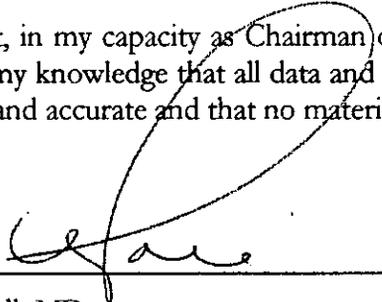
Substantial Equivalence The Clear-Vu System is substantially equivalent in terms of safety and effectiveness to the following predicate devices:

1. Defogging Heated Endoscopic Lens Protector (D.H.E.L.P.)/ K062779
New Wave Surgical Corp.
2. Endo-Scrub® 2 / K982594
Xomed, Inc.
3. SeeClear™ Laparoscopic Smoke Evacuation System / 510(k) Exempt
JLJ Medical Devices International, LLC

Technological Comparison The Clear-Vu System is substantially equivalent to the cited predicate devices in terms of intended use, and the technological differences are not significant relative to the safety or effectiveness of the new device.

Truthful and Accuracy Statement
(as required under 21 CFR § 807.87(k))

I certify that, in my capacity as Chairman of Minimally Invasive Devices, LLC, I believe to the best of my knowledge that all data and information submitted in the 510(k) Notification are truthful and accurate and that no material fact has been omitted.



Wayne L. Poll, MD

2/22/08
Date

K _____

(Premarket Notification [510(k)] Number) *

*For a new submission, leave blank.

Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter).

Executive Summary

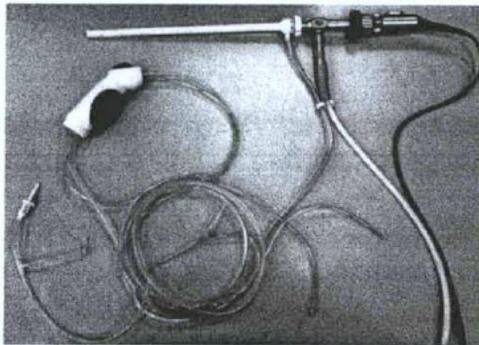
Clear-Vu System Minimally Invasive Devices, LLC

Indication for Use

Clear-Vu is a single-use, disposable laparoscopic accessory device that is intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site.

Device Description

The Clear-Vu System consists of a multi-lumen sheath assembly mounted on the shaft of the laparoscope with standard tubing connecting the device to the existing CO₂ insufflation circuit and the existing surgical irrigation system. Specifically, the Clear-Vu System consists of: 1) a Sheath Assembly for laparoscopes with 0°, 30° or 45° angled tips; a Handle Assembly; and 3) Tubing and Connectors, including a connector to the insufflator, a water spike to the pressurized saline, and a connector to the trocar.



Clear-Vu System (Laparoscope and Camera attached for reference)

To accomplish laparoscope (b)(4) Trade Secret Process

[REDACTED] To accomplish lens cleaning when necessary, a user-actuated saline flush is directed through the device and across the laparoscope lens. The operator can then (b)(4) Trade Secret over the lens to further remove debris and/or residual saline droplets.

Reason for this 510(k) Notification

MID submitted a 513(g) Request to FDA (C070324) to obtain a written statement from the Agency respecting the device classification and premarket regulatory controls applicable to this device. In response to the 513(g) Request, FDA confirmed the Clear-Vu System is an endoscope accessory in accordance with 21 CFR § 876.1500(b)(1), a Class II medical device subject to the general controls of the FD&C Act, including 510(k) notification.

Substantial Equivalence Comparison

An endoscope accessory, the Clear-Vu System is substantially equivalent to a combination of legally marketed devices as follows:

1. Defogging Heated Endoscopic Lens Protector (D.H.E.L.P.) / K062779
New Wave Surgical Corp.
2. Endo-Scrub® 2 / K982594
Xomed, Inc.
3. SeeClear™ Laparoscopic Smoke Evacuation System / 510(k) Exempt
JLJ Medical Devices International, LLC

The Clear-Vu System is substantially equivalent to a combination of predicate devices, and the technological differences between the Clear-Vu System and the cited predicates are not significant in terms of safety or effectiveness. To support the substantial equivalence claim, this 510(k) Notification includes a comparison of the Clear-Vu System to each of the cited predicates and a substantial equivalence discussion following FDA 510(k) Memorandum #K86-3 (Section 11). We believe this 510(k) Notification contains sufficient information to support a substantial equivalence determination by FDA.

Device Description

Clear-Vu System Minimally Invasive Devices, LLC

Background. The safety and efficacy of minimally-invasive laparoscopic surgical procedures can be significantly impacted by the degree to which the distal lens of the laparoscope can be maintained free of fog and surgical debris during the procedure. Differences in temperature and humidity between the operating room and the abdominal cavity can cause the formation of condensation on the lens and fogging, obscuring the surgical image. The surgeon's view can be similarly compromised by blood and surgical debris adhering to the laparoscope lens.

Beyond simple "tricks of the trade" that may give the surgeon temporary relief from such interference, effective defogging and cleaning currently require removal of the laparoscope from the trocar for access to the lens. After withdrawal from the trocar, the scope may be wiped clean or dipped in a solution for both cleaning and thermal equilibration before reinsertion. However, withdrawal of the laparoscope for cleaning prevents visualization of the surgical site and the procedure must be temporarily halted, which is especially problematic in the presence of active bleeding or other surgical crises. Surgeons will often press themselves to continue to operate with an inferior surgical image until cleaning of the lens becomes an absolute necessity. Moreover, laparoscope may require repeated removal from the trocar, e.g., 7 to 8 times per hour or more. During a 2-hour surgical procedure, it is not unusual for 15 to 30 minutes of that time to be consumed by repeated lens defogging and/or cleaning.

The effect of the compromised surgical view is a dramatic compromise in the continuity of a surgery and a predictable set of significant consequences, from an increasingly frustrated and distracted surgical team, to a negative effect on operating room throughput. While no definitive studies have been conducted, it is also possible that surgical outcomes may also be compromised by increased infection rates, surgical mistakes, and prolonged anesthesia due to the need to repeatedly clean and defog the laparoscope.

The images in Figure 1 clearly depict the problem of lens fogging:

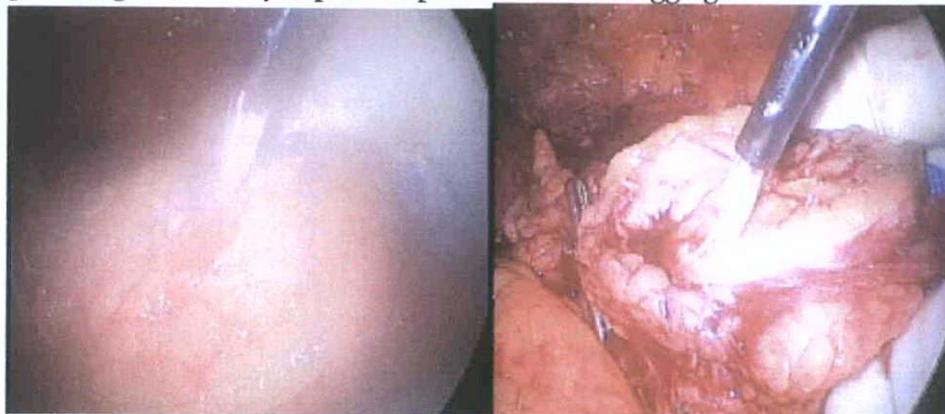


Figure 1: 'Before and After' Laparoscope Lens Defogging.

Device Description. Clear-Vu is a single-use, disposable laparoscopic accessory device that is intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site. The device consists of a multi-lumen sheath assembly mounted on the shaft of the laparoscope with standard tubing connecting the device to the existing CO₂ insufflation circuit and the existing surgical irrigation system (Refer to Figure 2).

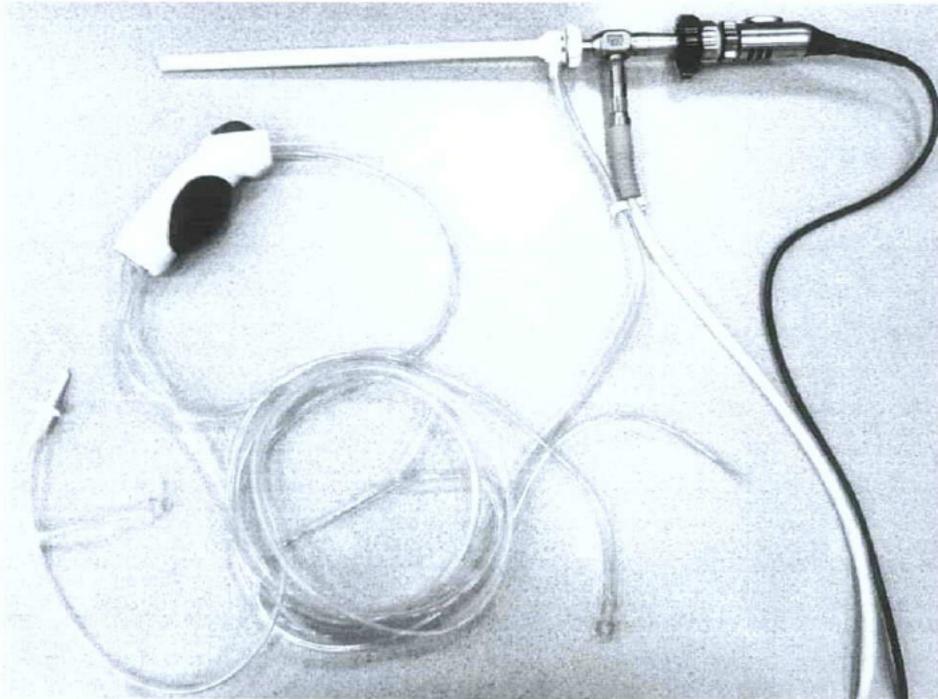


Figure 2: Clear-Vu System (Laparoscope and Camera attached for reference)

The Clear-Vu System will consist specifically of the following:

- Sheath Assembly (Figure 3) for laparoscopes with 0°, 30° or 45° angled tips (Figure 4);
- Handle Assembly (Figure 5);
- Tubing and Connectors, including Connector to Insufflator, Water Spike to Pressurized Saline, and Connector to Trocar (Figure 6).

(b)(4) Trade Secret Process

To accomplish lens cleaning when necessary, a user-actuated saline flush is directed through the device and across the laparoscope lens. The operator can then prompt a burst of CO₂ over the lens to further remove debris and/or residual saline droplets.

Video Demonstration. The compact disc enclosed with this 510(k) Notification contains a video demonstration of the effectiveness of the Clear-Vu System.

(b)(4) Trade Secret Process - Design

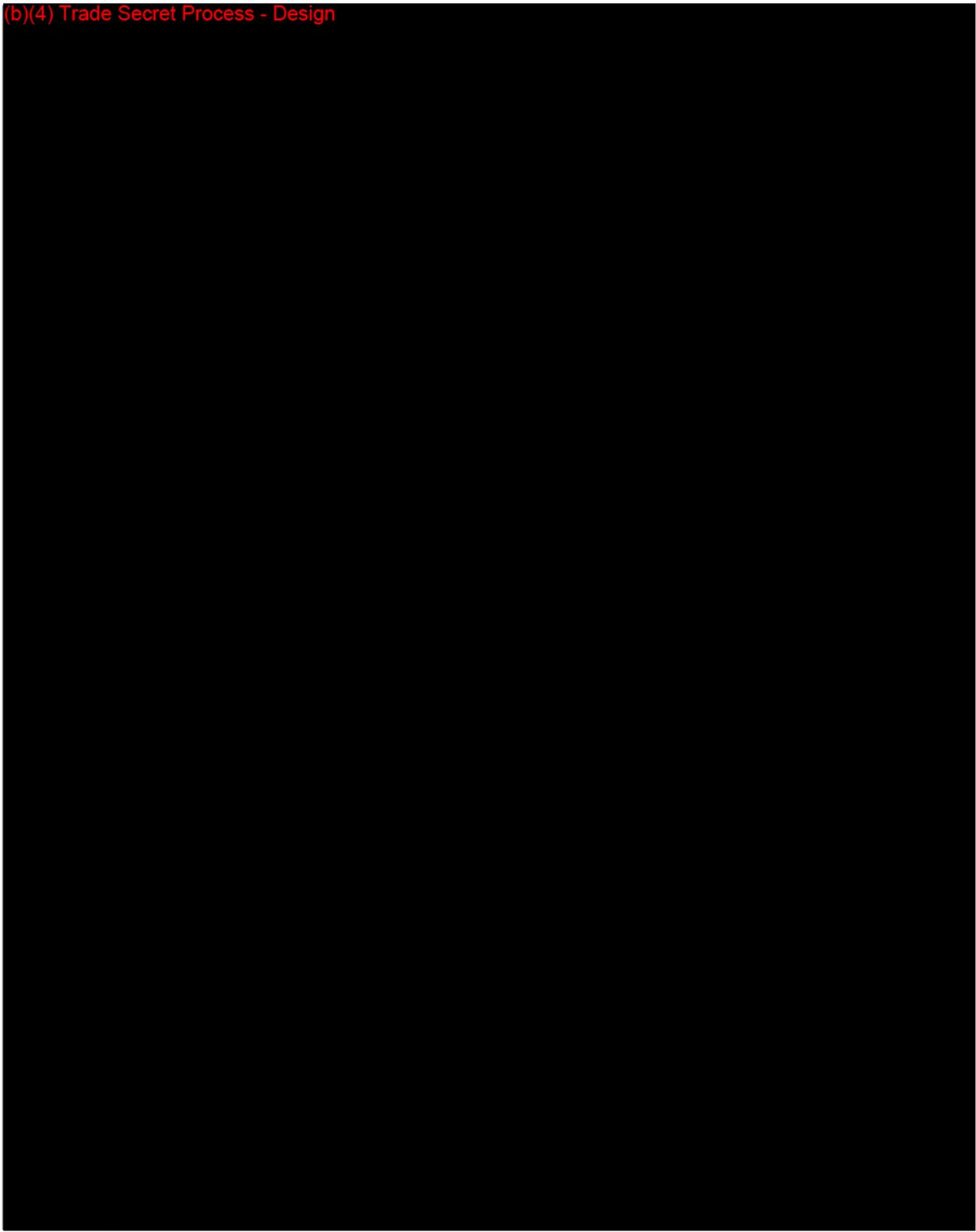


Figure 2: Clear-Vu Sheath Assembly

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(b)(4) Trade Secret Process - Design

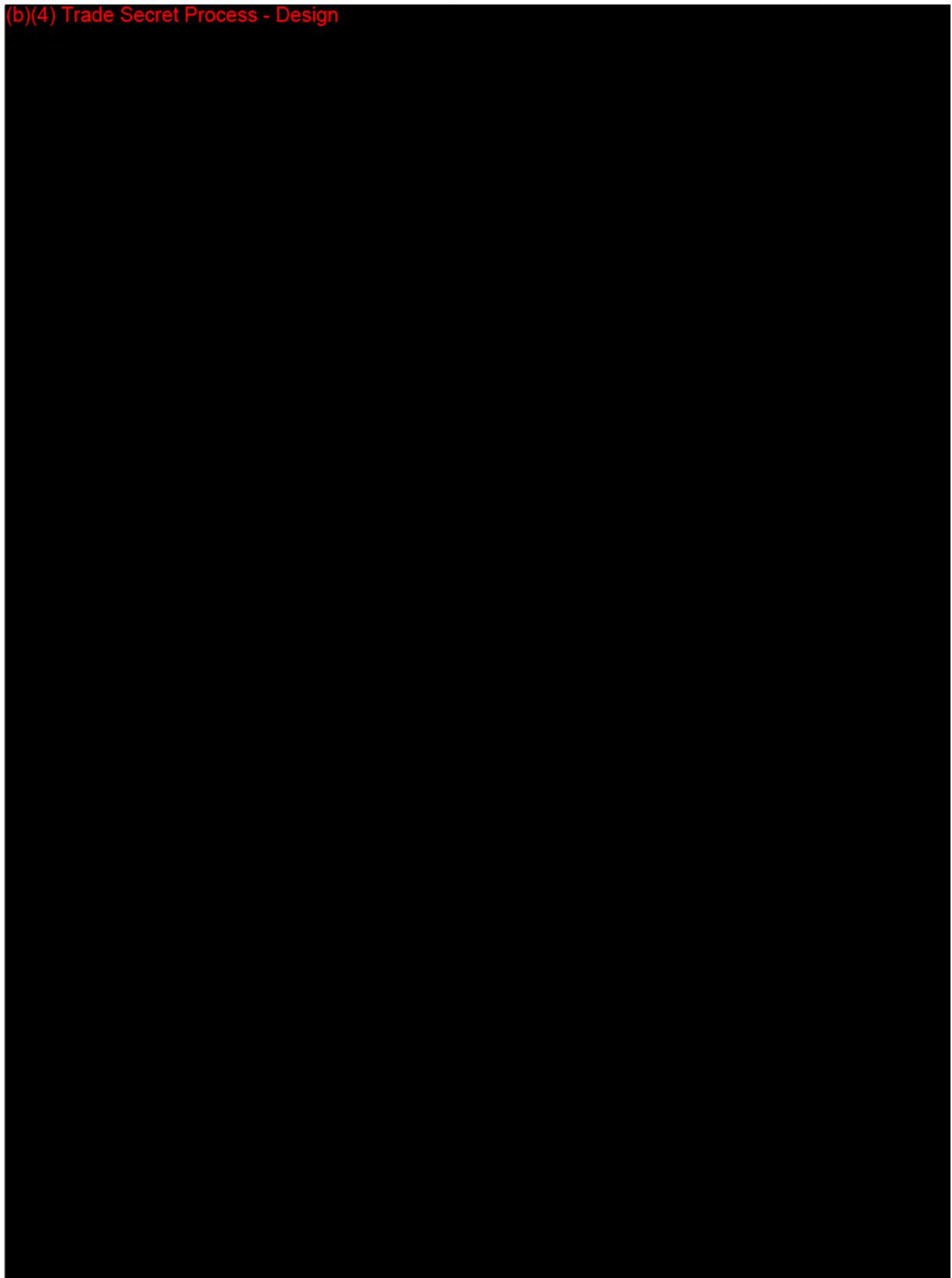


Figure 3: Clear-Vu Sheath Tip Configurations

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(b)(4) Trade Secret Process - Design

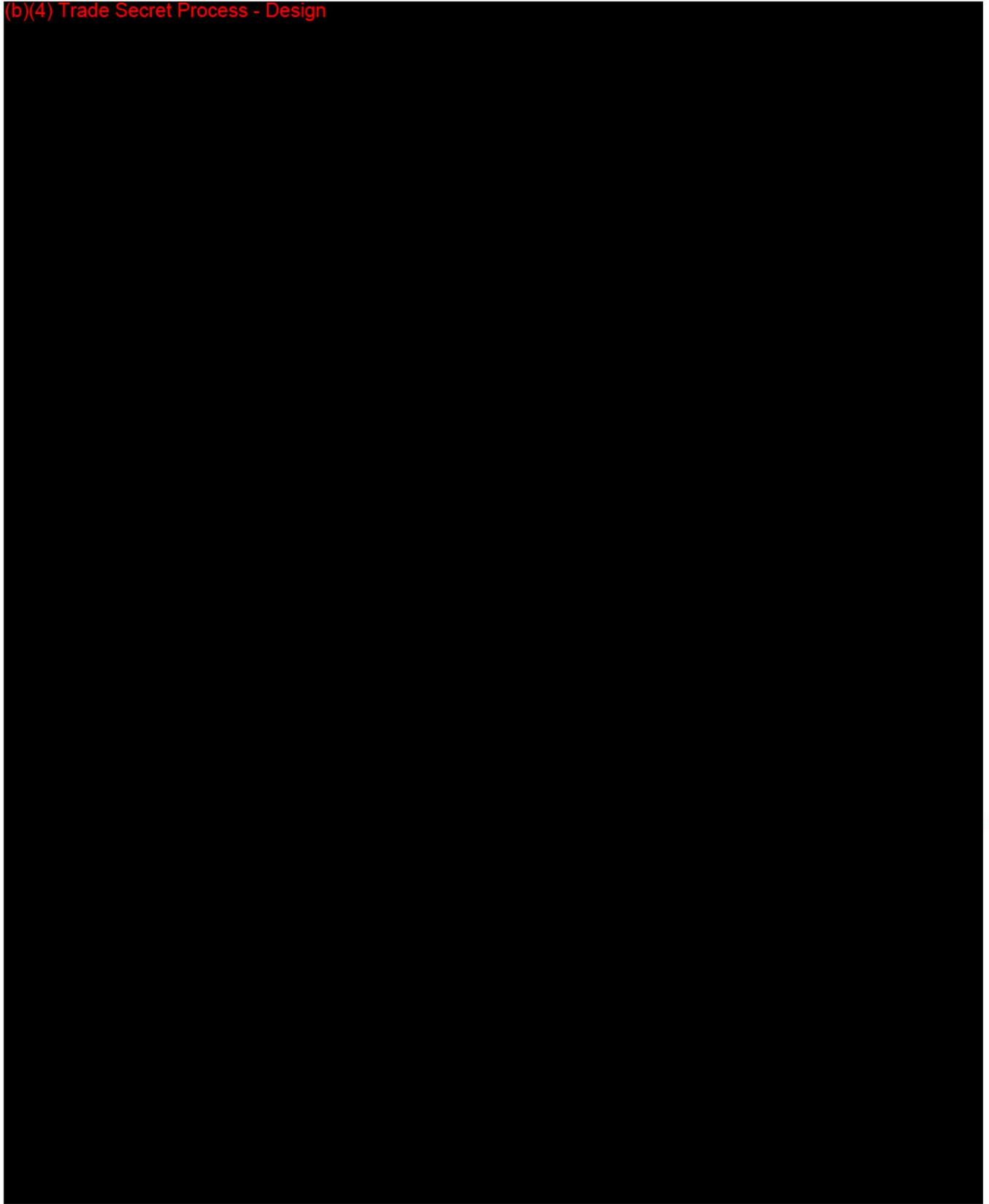


Figure 4: Clear-Vu Handle Assembly

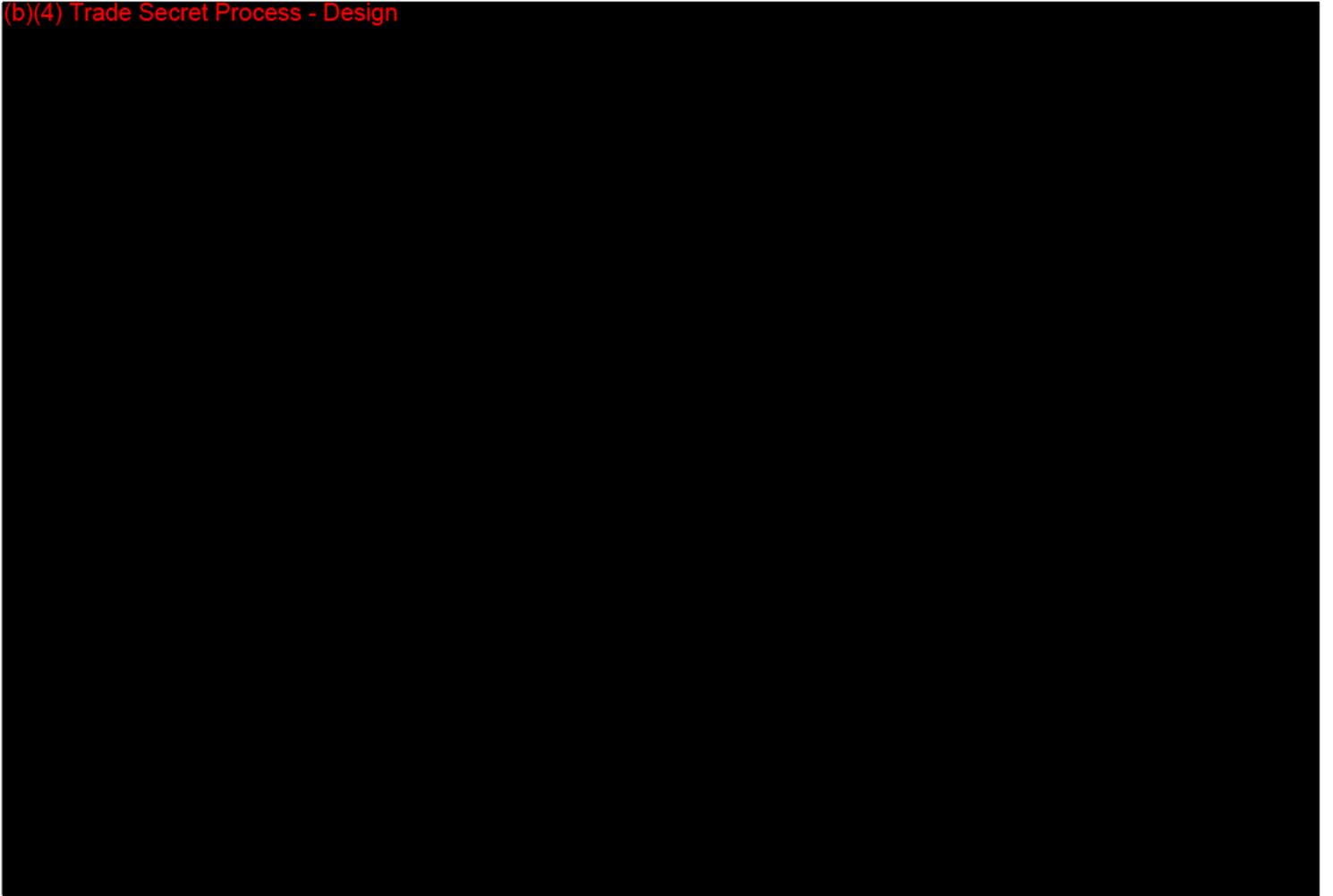
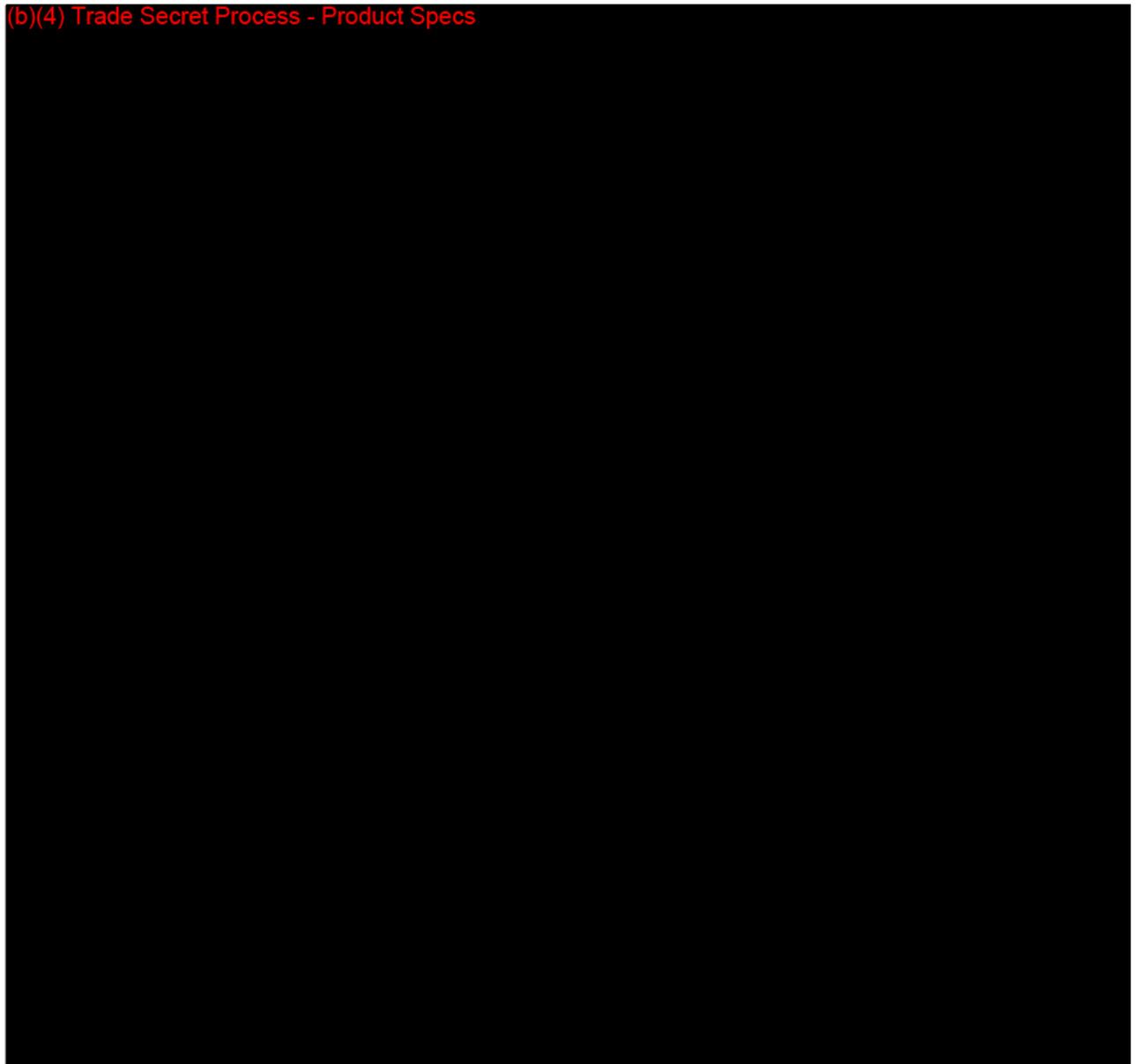


Figure 5: Clear-Vu System Tubing and Connector Schematic

Materials. Table 1 below shows the materials of which the Clear-Vu device are constructed which have tissue communication, each of which is commonly used in such applications. Section 12 identifies the materials with tissue contact and addresses biocompatibility.

Table 1: Materials of Construction with Tissue Communication

(b)(4) Trade Secret Process - Product Specs



Device Packaging. The Clear-Vu System procedure kit is packaged with one sheath assembly (zero degree), one handle assembly and ancillary tubing and connectors in a formed PETG plastic tray with an adhesive coated Tyvek® heat sealed lid. This package is contained within a Tyvek/film chevron-style pouch, using a heat seal adhesive coating to bind the layers. Refer to Figure 6. The use of this packaging configuration ensures stability of the components and integrity of the package. In addition, the use of Tyvek stock produces a fiber free peel, and all packaging materials have a long history of being radiation sterilized. On each product package is the primary device label (refer to Section 10.). The non-Tyvek material is clear to allow visualization of the product. Additional procedure kits including only 30° and 45° angled sheath assemblies are packaged in the same tray and pouch with appropriate labeling.



Figure 6: Clear-Vu System Sterile Packaging

The pouched/trayed packages will be placed in die cut paperboard-folding cartons that are labeled to identify the Clear Vu System and manufacturing information. The configurations are identified in Table 2.

Table 2. Clear-Vu System Packaging Configurations

Catalog Number	Description	Packaging Levels
CVL-01-1000	Procedure Tray with one sheath assembly (zero degree), one handle assembly and ancillary tubing and connectors	Components placed in a formed PETG plastic tray that is placed within pouch
	Unit Carton	Each unit tray placed in a die cut paperboard carton
	Sales Carton	Multiple unit trays in paperboard carton placed in a paperboard overpack to create sales unit
	Shipping Container	Multiple sales units placed in a corrugated shipping unit
CVL-01-1030	Procedure Tray with one sheath assembly (30 degree)	Components placed in a formed PETG plastic tray that is placed within pouch
	Unit Carton	Each unit tray placed in a die cut paperboard carton
	Sales Carton	Multiple unit trays in paperboard carton placed in a paperboard overpack to create sales unit
	Shipping Container	Multiple sales units placed in a corrugated shipping unit
CVL-01-1045	Procedure Tray with one sheath assembly (45 degree)	Components placed in a formed PETG plastic tray that is placed within pouch
	Unit Carton	Each unit tray placed in a die cut paperboard carton
	Sales Carton	Multiple unit trays in paperboard carton placed in a paperboard overpack to create sales unit
	Shipping Container	Multiple sales units placed in a corrugated shipping unit

Proposed Device Labeling

Clear-Vu System Minimally Invasive Devices, LLC

Proposed labeling for the MID Clear-Vu System is provided for review, including the proposed primary device label, proposed instructions for use, and proposed promotional information, as follows:

Proposed Primary Device Label

The primary device label will be placed on the Tyvek® pouch used to package the Clear-Vu System and will contain, at a minimum, the following information:



Clear-Vu™ Laparoscopic Defogging & Cleaning System (CVL-01-1000/1030/1045)

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

Contents: 1 Procedure Tray

Lot No. XXXX

Single Patient Use. Do Not Reuse.

Sterile (R). Sterility guaranteed unless packaged opened or damaged.



Refer to Instructions for Use

Manufactured for: Minimally Invasive Devices, LLC
1275 Kinnear Road
Columbus, Ohio 43212

Proposed Instructions for Use

A copy of draft instructions for use for the MID Clear-Vu System is attached.

Proposed Promotional Information

MID has not yet prepared promotional literature in support of the commercialization of the Clear-Vu System. However, MID intends to utilize the following promotional themes:

- Clear-Vu is a laparoscopic accessory device that:
 - enhances patient safety by retarding and defeating the loss of visualization during minimally invasive surgery due to the fogging or dirtying of the laparoscopic lens;
 - saves time by eliminating most needs to remove, clean the scope's lens, re-insert the scope into the abdomen and re-acquire visualization of the surgical site;
 - enhances efficiency by restoring continuity of the surgical case and eliminates a source of distraction and frustration for the surgical team.

- Clear-Vu ^{NO} eliminates intra-operative fogging of the laparoscopic lens and offers a means for rinsing the lens of blood and most surgical debris without withdrawing the scope from the surgical site.
- Clear-Vu serves minimally invasive surgeries by integrating with the established suite of surgical devices and instrumentation being used, requiring no incremental power source or necessitating appreciable changes in the process or practice of the surgical team.
- Clear-Vu further ^{NO} enhances patient safety by maintaining a clear and stable visualization of the surgical field, even in times of active bleeding and other surgical crises.
- By eliminating most of the frequent and time-consuming need to remove the laparoscope for cleaning during surgery the continuity of the surgical procedure is maintained, stress and frustration of the surgical team is reduced, anesthesia time is shortened, and Operating Room throughput is potentially enhanced.
- Quick and simple set up. Easy to use. Fully disposable.



Clear-Vu™ Laparoscopic Defogging & Cleaning System (CVL-01-1000/1030/1045)

Instructions for Use

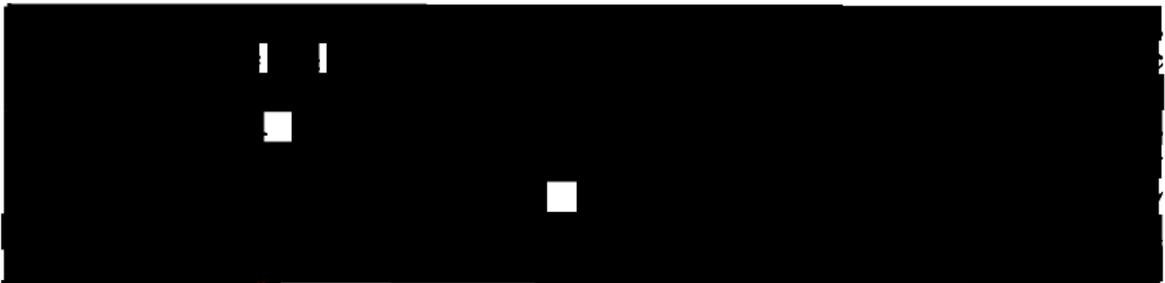
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Description

The Clear-Vu System (Clear-Vu) is a sterile, single-use, disposable laparoscopic accessory device that facilitates intra-operative defogging and cleaning of the lens of a laparoscope during minimally invasive surgery while maintaining visualization of the surgical site. Clear-Vu consists of a multi-lumen sheath assembly that mounts over the shaft of the laparoscope. A tubing set connects the device to the existing CO₂ insufflation circuit and to the existing surgical irrigation system.

Design & Function

Clear-Vu provides a method for maintaining clear visualization of the surgical site without removing the laparoscope from the abdominal cavity for the purpose of cleaning or de-fogging its lens. It is designed to integrate with the existing suite of minimally invasive instrumentation, to not interfere with the surgical set-up, and to require little-to-no change in the process or practice of the surgical team.

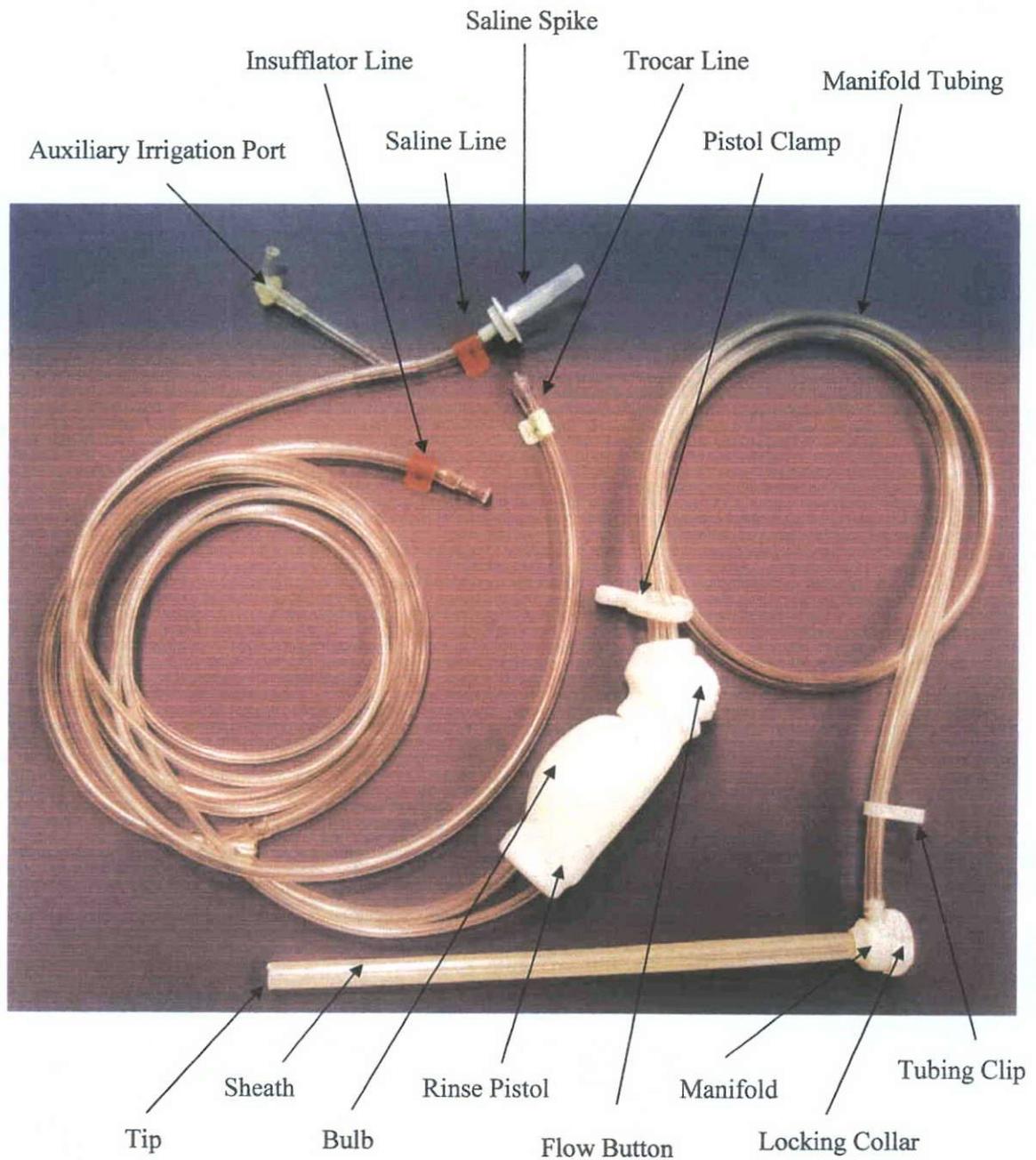


(b) As blood or other debris may nonetheless contact and adhere to the lens during surgery, the device permits cleaning when necessary with the simple actuation of a saline flush. This flushing mechanism similarly draws from the pressurized saline reservoir of the surgical irrigation circuit and directs a small volume through the device and across the laparoscopic lens. As desired, the operator can then prompt a burst of gas over the lens to further remove debris and/or residual saline droplets. Visualization is restored rapidly and without removal of the laparoscope from the abdomen.

How Supplied

The disposable Clear-Vu System comes packaged in a sterile tray, the tray inside a peel away pouch, and consists of the following:

- One Clear-Vu Sheath & Manifold Assembly
- One Rinse Pistol Assembly
- Pre-installed Ancillary Tubing and Connectors including:
 - Line & connector to insufflator tubing
 - Line & connector to insufflation trocar
- Line & spike to pressurized saline, including Y-connector & port for irrigator spike.)



Indication for Use

The Clear-Vu is a single-use disposable laparoscopic accessory device that is intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site.

Warnings

- Clear-Vu is a single-use, disposable device that is not intended to be reused. Do not reuse this device. Any attempt to clean, re-sterilize and reuse the device may compromise its safety or effectiveness and may cause serious injury to a patient. Dispose of all open products, used or unused, after the procedure is concluded.

Precautions

- Sterile technique should be used in opening the package. Do not use if the package is found opened or damaged.
- Care should be taken to avoid damage to the device's sheath or tip, especially when inserting the laparoscope into the sheath. Do not use if the tip is missing or damaged.
- Ensure that the Clear-Vu sheath has been properly locked onto the shaft of the laparoscope. If used when not secured, Clear-Vu's functionality may be compromised, depth of laparoscopic penetration may be adversely affected, and the Clear-Vu tip may be damaged.
- Given its specific dimensions, the Clear-Vu sheath will accommodate a 10mm laparoscope (outside diameter) and the Clear-Vu/laparoscope assembly must be used in combination with a 12mm (inside diameter) optical trocar.
- Use prior to the last day of the month of expiration.
- Review the Instructions for Use before using Clear-Vu.

Directions for Use

Caution: The following directions for use are provided to clarify the set up and use of the Clear-Vu system. This device should be used only in concert with widely accepted good surgical practices, using sterile technique, and only by qualified technicians/operating room personnel with appropriate training. (Components of the Clear-Vu device are identified below in **bold**.)

OPENING THE PACKAGE

1. Peel open the outer pouch at the point indicated and remove the sterile tray. Strip off the tray's Tyvek lid and remove components from the tray. (Note: Contents of both the pouch and of the tray are sterile. In opening the package, O.R. personnel should use sterile technique and proceed in compliance with their established institutional protocols.)
 - a. Take care when removing Clear-Vu's **Sheath** and **Manifold** assembly from its tray so as to prevent damage to the walls of the **Sheath** or to its **Tip**.
 - b. Do not allow the attached tubing and/or connectors to drop below the sterile field prior to making necessary connections.

SET UP (Sequence of steps 2-6 may be modified to suit operating room practice)

2. Spike Clear-Vu's **Saline Line** (tagged & labeled) into the port of a pressurized irrigation bag. Insure that a proper connection is made and that no leaks are visible.
3. If desired, spike the water line of a suction/irrigation system into Clear-Vu's **Auxiliary Irrigation Port** provided via the Y-connector.
 - a. If connection cannot be made, use an additional irrigation bag.
4. Connect Clear-Vu's **Insufflator Line** (tagged & labeled) to the insufflator output or to the line that would formerly have been connected to the stopcock on the insufflation trocar.
 - a. The Insufflator Line comes with an attached luer connector. This can be removed to accommodate a different style connection if desired.
5. Connect Clear-Vu's **Trocar Line** (tagged & labeled) to the stopcock on the insufflation trocar once the trocar has been properly introduced through the abdominal wall. It is recommended that the optical trocar NOT be used as the insufflation trocar. (Note: The Trocar Line remains on the sterile field after the connection is made.)

6. Clip Clear-Vu's **Rinse Pistol** assembly to an accessible place on the sterile field of the surgical table. Use the attached **Pistol Clamp** to properly secure it to the surgical drape to prevent it from inadvertently falling off the sterile field.
 - a. The Rinse Pistol only needs to be accessed when a saline flush to the laparoscopic lens is needed. There is no need to constantly grasp or otherwise tend to the Rinse Pistol throughout the course of surgery.
7. While gently pressing the **Tip** of Clear-Vu's **Sheath** assembly against one hand or fingertip, carefully insert the laparoscope down into the **Sheath** until the lens and distal rim of the scope is seated on the back of Clear-Vu's **Tip**. The scope will "bottom out" inside the device. **Caution: Do not use excessive force when inserting the scope into the sheath, or "slam" the laparoscope into the back of Clear-Vu's Tip.** The scope should slide smoothly through the shaft of the device.



8. While holding the laparoscope fully inserted into the **Sheath**, and supporting the **Manifold** of the **Sheath** by hand (see diagram), rotate the **Locking Collar** on the **Sheath** assembly clockwise approximately one-third (1/3) of a turn until a firm stop is felt.



This locks the scope to the Clear-Vu device. Note: Once locked, any rotation or up/down movement of the laparoscope inside the Sheath will not be possible without potentially stripping the locking mechanism. Be certain to unlock the scope before attempting to rotate or otherwise move it within the sheath.

- a. Before locking, check to see if any part of the Tip is present in the view of the scope (as projected on the monitor). If so, simply rotate the shaft of the scope inside the Sheath and Manifold assembly until the image of the Tip is eliminated.
- b. It may be considered useful to align Clear-Vu's **Manifold Tubing** (air & saline lines) in parallel with the cord of the laparoscope's light source before locking. Use the supplied **Tubing Clip** to attach the tubing to the cord and maintain this alignment.
- c. Once locked into place, examine the tip end of the Clear-Vu and scope assembly. To ensure proper function, Clear-Vu's **Tip** should be securely fastened to its **Sheath** and no space or visible gap should be observed between the distal rim of the scope's shaft and the **Tip** of the device.

OPERATING THE DEVICE

9. With the insufflating trocar in place and the **Trocar Line** properly connected, switch on the insufflator to inflate the abdominal cavity as usual.
10. Insert the scope and the attached Clear-Vu **Sheath** through a 12mm optical trocar and acquire visualization of the surgical site as usual. **Caution: Do not use excessive force when inserting the Sheath and scope assembly into the trocar. The assembly should slide smoothly down the trocar.** During the normal course of surgery, the Clear-Vu device will operate automatically to prevent fogging. Operate the laparoscope as normal. No user intervention is required.
11. As intra-operative visualization may be impaired due to the adherence of blood or surgical debris on the laparoscopic lens, depress the **Flow Button** on the **Rinse Pistol** to activate a pressurized flow of saline across the lens. The saline flow will continue as long as the **Flow Button** is depressed, and will stop when the **Flow Button** is released.
 - a. Typically, only a momentary flow (2-3 seconds) of saline will be sufficient to effectively rinse the lens of the laparoscope. Multiple rinses may be necessary.
12. To blow off any residual saline which may be present on the lens after rinsing, squeeze the **Bulb** on the **Rinse Pistol** with a firm, sudden force creating an air burst. Several bursts may be required to remove all droplets of saline. Another flush of saline, followed by another burst from the **Bulb** may also prove useful in the case of a stubborn water droplet interfering with visualization. Due to the continuous laminar flow across the lens, small droplets will disappear spontaneously after a few seconds.
 - a. **For fatty substances, external cleaning of the lens may sometimes be required.** In this case, carefully withdraw the scope/Sheath assembly from the trocar and clean the lens with a **wet 4x4 gauze pad**. Before re-insertion, re-examine the assembly to ensure that there is no visible gap between the end of the scope and the **Tip** of the device per Section 8.c. of these instructions
 - b. Excessive movement of the **Rinse Pistol** and/or tubing lines may cause a small droplet of saline to appear on the lens without depressing the **Flow Button**. Should this occur, squeeze the **Bulb** to remove this droplet.

REMOVAL/ DISASSEMBLY

13. At the conclusion of surgery, withdraw the scope/Clear-Vu assembly from the trocar. Unlock the assembly by rotating the **Locking Collar** counterclockwise approximately 1/3 of a turn. Slide the laparoscope out of the **Sheath**. **Caution: Care should be taken not to inadvertently drop and damage the laparoscope once the assembly has been unlocked.**

14. Disconnect the tubing set from the insufflating trocar, the insufflator output circuit, and the saline reservoir.
15. Dispose of the entire Clear-Vu device and ancillary tubing set. **Caution: The used Clear-Vu device should be treated as bio-hazardous waste and disposal should be in accordance with established institutional protocols.**

TROUBLESHOOTING

16. If insufflation of the abdomen has been achieved and the laparoscopic view fogs and fails to clear within several seconds after insertion of the scope/Clear-Vu assembly, try one or more of the following:
 - a. Withdraw the scope/Clear-Vu assembly from the trocar and examine the **Tip**. No visible gap should exist between the **Tip** and the lens/distal rim of the scope. If a gap does exist, unlock the assembly by rotating the **Locking Collar** counter-clockwise, pull the scope back several inches within the Clear-Vu **Sheath**, and reseat it by repeating steps 7-8.
 - b. Check to make sure there are no kinks or obstructions in the CO₂ line from the insufflator to the Clear-Vu device.
 - c. Add additional venting to the system by slightly opening the stopcock of an adjacent trocar so as to create an air leak.
 - d. Withdraw the assembly from the trocar and wipe the lens with a clean 4x4. (This may conceivably be necessitated by an unusually large amount of moisture which overwhelms the operation of Clear-Vu.)
17. If operation of the **Rinse Pistol** and depression of the **Flow Button** fails to produce a flow of saline across the laparoscope's lens, try one or more of the following:
 - a. Check that the spike connection to the saline reservoir/bag is made properly.
 - b. Check that there are no apparent leaks in the water circuit.
 - c. Check that the tubing is not kinked or obstructed.
 - d. Check that the saline reservoir/bag is adequately pressurized.
 - e. Ensure that the laparoscope's lens is properly seated behind the **Tip** of the device, per instruction 16.a. above.
18. If insufflation of the abdomen cannot be achieved and the insufflator is operating properly, check to make sure there that the proper connection has been made between the **Insufflator Line** and the insufflator, that there are no kinks or obstructions in the CO₂ line from the insufflator to the Clear-Vu device, and that the proper connection has been made between the **Trocar Line** and the insufflating trocar.

STERILE R

Sterile. Sterilized by gamma radiation. Do not use open or damaged packages.

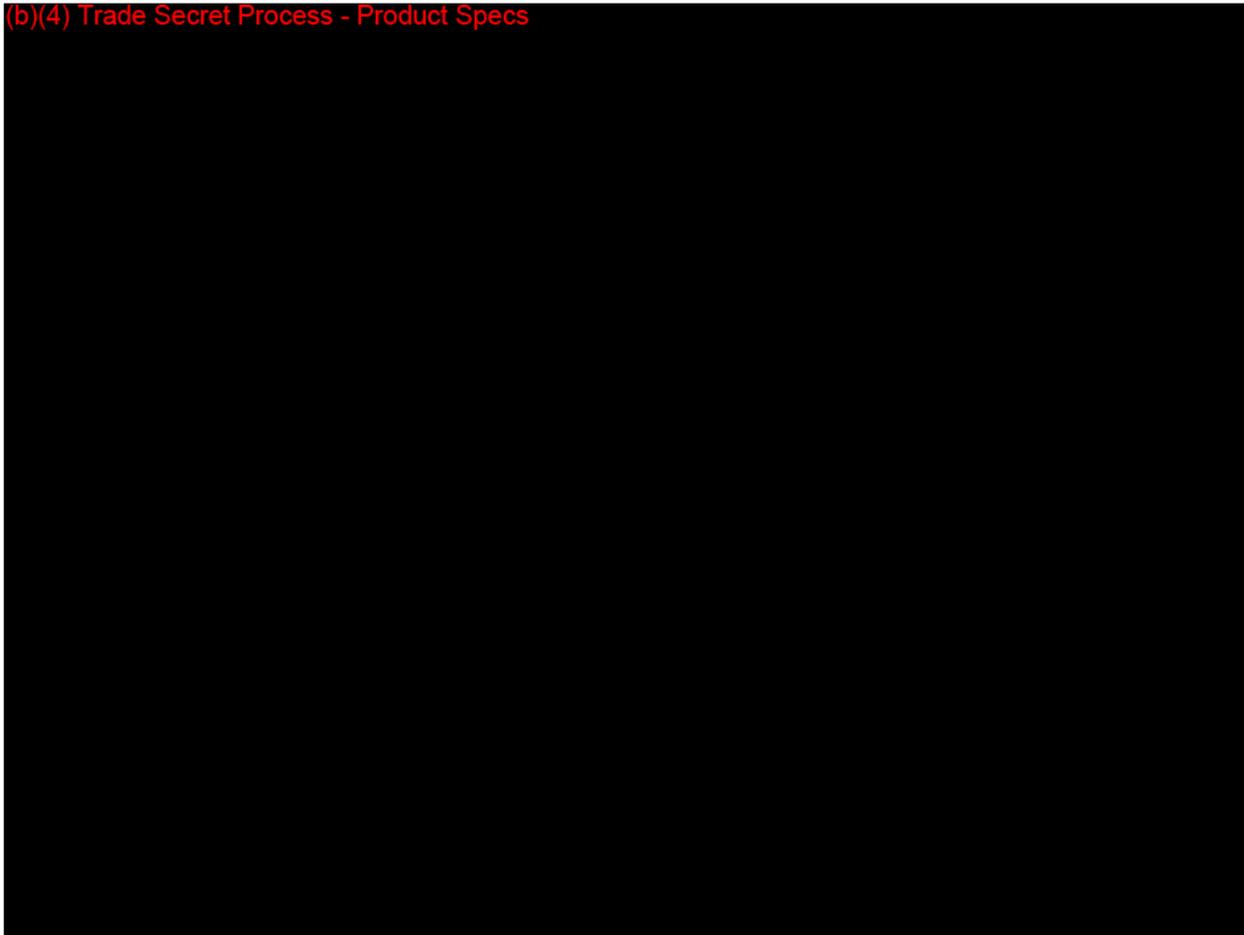


Manufactured for:
Minimally Invasive Devices, LLC
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Columbus, OH 43212
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Fax: (614) 889-7630
11238 Rev. 01

Sterilization

Clear-Vu System
Minimally Invasive Devices, LLC

(b)(4) Trade Secret Process - Product Specs



Biocompatibility

Clear-Vu System
Minimally Invasive Devices, LLC

(b)(4) Trade Secret Process - Product Specs



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Substantial Equivalence Comparison

Clear-Vu System Minimally Invasive Devices, LLC

The Clear-Vu System. The Clear-Vu System is a single-use, disposable laparoscopic accessory device that is intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site. Clear-Vu consists of a multi-lumen sheath assembly mounted on the shaft of the laparoscope, which connects to the existing CO₂ insufflation circuit to defog the laparoscope lens and diverts surgical debris, and connects to the existing surgical irrigation system to clean the lens via saline flush.

In accordance with FDA's November 30, 2008 response to MID's 513(g) Request C070324, "*the MID Clear-Vu System falls within Title 21 of the Code of Federal Regulations (CFR) 876.1500(b)(1), Endoscope and accessories.*" We believe the appropriate FDA product codes for our device to be KOG (endoscope and/or accessories) and GCJ (laparoscope, general and plastic surgery).

Predicate Devices. We believe the Clear-Vu System is substantially equivalent to the combination of the following legally marketed (predicate) devices in terms of safety and effectiveness:

1. Defogging Heated Endoscopic Lens Protector (D.H.E.L.P.) /New Wave Surgical Corp. / K062779

In accordance with the 510(k) Summary for this predicate device, "*The Defogging Heated Endoscopic Lens Protector (D.H.E.L.P.) is a small, sterile, disposable, multi-function device intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens for 5mm and 10mm scopes. It is designed to heat an anti-fog surfactant and maintains this solution above body temperature for over 4 hours. This is intended to reduce fogging better than other anti-fog methods by combining both heat and the antifog solution.*" A copy of sample labeling for this predicate device is attached.

2. Endo-Scrub® 2 / Xomed, Inc. / K982594

In accordance with the 510(k) Summary for this predicate device, "*The Endo-Scrub 2 Pump is an AC-powered microprocessor controlled pump with adjustable irrigation and aspiration cycles. Pump action initiated by depression of the foot control or optional clip-on sheath switch results in a "scrub cycle."* The Endo-Scrub 2 Sheath consists of an anodized aluminum sheath attached to an ABS handle with a Luer connector for irrigation tubing. The Endo-Scrub 2 is intended to clear accumulated debris from the inserted end of the scope without removing the scope from the surgical site, maintaining visualization during the procedures. It is indicated for use with mechanical endoscopic sinus instruments and with fiber optic lasers in endoscopic nasal and sinus surgery." A copy of sample labeling for this predicate device is attached.

3. SeeClear™ Laparoscopic Smoke Evacuation System / JLJ Medical Devices International, LLC / 510(k) Exempt

In accordance with the manufacturer's promotional literature for this predicate device, *"The SeeClear™ laparoscopic smoke evacuation system is a patented passive filtration system that provides continuous, automatic clearance of smoke, bioaerosols and mist during laparoscopic procedures – without loss of pneumoperitoneum. Simply attach the SeeClear™ filter system to an opened side port of a trocar. Surgical plume generated within the peritoneal cavity is pushed out by the elevated intraperitoneal pressure. No suction is required. Biocontaminants are captured. CO2 is deodorized and returned to ambient air. [SeeClear] improves visual clarity by continuously clearing away smoke, bioaerosols and mist from the field of view, reduces procedure time by eliminating the need to remove the laparoscope to clean the lens or to wait for the surgical plume to clear, and prevents medical staff exposure to surgical plume generated during laparoscopic procedures."* A copy of sample labeling for this predicate device is attached.

Substantial Equivalence. The following information demonstrates the substantial equivalence of the Clear-Vu System to the cited predicate devices:

1. A Substantial Equivalence Comparison Table, which compares the Clear-Vu System to each of the cited predicate devices with respect to important device characteristics; and
2. A discussion of the substantial equivalence of the Clear-Vu System to the cited predicate devices in accordance with the general criteria established in FDA's 510(k) Memorandum #K86-3, *Guidance on the CDRH Premarket Notification Review Program*.

Substantial Equivalence Comparison Table

Device Name	Clear-Vu System	Defogging Heated Endoscopic Lens Protector (D.H.E.L.P.)	Endo-Scrub® 2 Lens Cleaning System	SeeClear™ Laparoscopic Smoke Evacuation System
Sponsor Name	Minimally Invasive Devices, LLC	New Wave Surgical Corporation	Xomed, Inc.	JLJ Medical Devices International, LLC
510(k) Number	<i>This 510(k)</i>	K062779	K982594	<i>N/A - 510(k) Exempt</i>
Device Classification Regulation	21 CFR § 876.1500(b)(1)	21 CFR § 876.1500(b)(1)	21 CFR § 874.4760	21 CFR § 876.1500(b)(2)
Common Name	Laparoscope lens cleaning and de-fogging device	Laparoscope lens cleaning and de-fogging device	Suction/irrigation device	Laparoscopic surgical plume filter
Classification Name	Endoscope and accessories	Endoscope and accessories	Nasopharyngoscope (rigid) and accessories	Endoscopic smoke removal tube
Product Code(s)	GCJ, KOG	GCJ, KOG	EOB	FCZ
Device Description	Single-use disposable laparoscopic accessory device that connects to the existing insufflation circuit surgical irrigation system. The device prevents fogging and deflects blood and surgical debris by a continuous CO ₂ flow across the distal lens and removes blood and surgical debris from the lens as needed by directing a saline flush or CO ₂ burst over the lens. The device performs its defogging and cleaning functions without the need for withdrawal from the surgical trocar thereby maintaining the surgical image.	Small, sterile, disposable, multi-function device designed to store and apply anti-fog surfactant solutions to the distal lens of endoscopes. This is intended to reduce fogging on endoscopes by applying anti-fog solution to the distal lens.	AC-powered microprocessor controlled pump with adjustable irrigation and aspiration cycles. Pump action initiated by depression of the foot control or optional clip-on sheath switch results in a "scrub cycle." The Endo-Scrub 2 Sheath consists of an anodized aluminum sheath attached to an ABS handle with a Luer connector for irrigation tubing.	Passive filtration system that provides continuous, automatic clearance of smoke, bioaerosols and mist during laparoscopic procedures without loss of pneumoperitoneum. Device is attached to an opened trocar side port. Surgical plume generated within the peritoneal cavity is pushed out by the elevated; CO ₂ is deodorized and returned to ambient air.

CONFIDENTIAL

Device Name	Clear-Vu System	Defogging Heated Endoscopic Lens Protector (D.H.E.L.P.)	Endo-Scrub® 2 Lens Cleaning System	SecClear™ Laparoscopic Smoke Evacuation System
Intended Use / Indications for Use	To facilitate intraoperative defogging and cleaning of the distal lens of a rigid laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site.	To be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens, white-balance the scope, clean and protect the scope, and eliminate the fire hazard from the fiber-optic light.	To clear accumulated debris from the inserted end of the nasopharyngoscope without removing the scope from the surgical site, maintaining visualization during nasal and sinus surgical procedures.	To remove surgically produced smoke, aerosols and odors during laparoscopic procedures.
Prescription Device?	Yes	Yes	Yes	Yes
Mechanism of Action	Prevents fogging and deflects surgical debris by pressurized CO2 from insufflation circuit flowing across lens. Removes surgical debris from lens by the pressurized CO2 or manually pressurized saline flush.	Prevents fogging by lens exposure to anti-fogging solution elevated above body temperature.	Clears accumulated debris from nasopharyngoscope by irrigation of scope lens tip with pump-controlled delivery and removal of saline solution.	Surgically produced smoke, aerosols and odors from peritoneal cavity filtered through device by positive CO2 insufflation pressure and vented into ambient air.
Cleaning Solution	Saline surgical irrigation fluid	Proprietary anti-fog solution	Saline surgical irrigation fluid	N/A
Cleaning Surface	N/A	MicroPad microfiber surface	N/A	N/A
Power Source	N/A-Not electrically powered	Battery-powered	Electrically-powered (120 V)	N/A - Not electrically powered
Software Controlled?	No	No	Yes	No
Devices Used With	Standard rigid 10mm laparoscopes, with 0°, 30° and 45° angle tips	Standard rigid laparoscopes, 5-10mm, any angle tips	Standard rigid nasopharyngoscopes, 2.7 or 4.0mm, with 0°, 25°, 30°, 45° and 70° angle tips	Standard 5mm or 10mm trocars
No. of Uses	Single use / disposable	Single use / disposable	Reusable	Single use / disposable
Provided Sterile?	Yes	Yes	Device-No / Sheath-Yes	Yes

CONFIDENTIAL

Substantial Equivalence Discussion

Using the general criteria established in FDA's 510(k) Memorandum #K86-3, *Guidance on the CDRH Premarket Notification Review Program*, the substantial equivalence of the MID Clear-Vu System to the cited predicate devices is further demonstrated as follows:

New Device is Compared to Marketed Device.

The Substantial Equivalence (SE) Comparison Table above compares the Clear-Vu System to each of the cited predicate devices in terms of appropriate device characteristics.

③ Does New Device Have Same Indication Statements?

As shown in the SE Comparison Table:

- The Clear-Vu System indication statement is comparable to that of the D.H.E.L.P. device in that both devices are intended to defog and clean the distal lens of a rigid endoscope. Differences include the fact that Clear-Vu is intended for use with rigid laparoscopes while D.H.E.L.P. is intended for any rigid endoscope. Therefore, Clear-Vu has the same intended use as D.H.E.L.P. and may be substantially equivalent.
- The Clear-Vu System indication statement is comparable to that of the Endo-Scrub device in that both devices are intended to clean the distal endoscope lens. Differences include the fact that Clear-Vu is intended for use with rigid laparoscopes while Endo-Scrub 2 is intended for use with rigid nasopharyngoscopes, and that Clear-Vu also is intended to defog the lens. Therefore, Clear-Vu has the same intended use as Endo-Scrub 2 and may be substantially equivalent.
- The Clear-Vu System indication statement is not comparable to that of the SeeClear System. Clear-Vu is intended to defog and clean the distal lens of a rigid laparoscope while See-Clear is intended to filter surgically produced smoke, aerosols and odors from peritoneal cavity. The only commonality is both devices utilize the existing insufflation circuit to achieve its intended function without compromising the pneumoperitoneum. Clear-Vu does not have the same intended use as See-Clear, which is included in the SE analysis only for comparison of the technical characteristics described above.

⑤ Does New Device Have Same Technological Characteristics?

As shown in the SE Comparison Table:

- The technological characteristics of Clear-Vu are comparable to that of D.H.E.L.P. in that both devices utilize fluid to defog and clean the endoscope lens. Differences include the fact that Clear-Vu utilizes the insufflated CO₂ and surgical irrigation saline for this purpose, which eliminates the need to remove the laparoscope from the surgical site while D.H.E.L.P. utilizes a proprietary defogging/cleaning fluid and mechanical contact with a microfiber surface, which requires removal of the endoscope from the surgical site for defogging and cleaning.

- The technological characteristics of Clear-Vu are comparable to that of Endo-Scrub 2 in that both devices utilize the saline solution to clean the lens without the need to remove the endoscope from the surgical site. Differences include the fact that Clear-Vu also utilizes the insufflated CO2 to clean and defog the lens, and Endo-Scrub 2 utilizes an electrically-powered, software-controlled peristaltic pump to deliver and remove the saline solution.

⑥ Could the New Technological Characteristics Affect Safety and Effectiveness?

Maintenance of a clean and fog-free endoscope lens is critical to the safety and effectiveness of the endoscopic surgical procedure, but the method by which the lens of cleaned and defogged is not. However, a device which cleans and defogs the lens without the need for removal is likely to represent an enhancement with regard to the safety and effectiveness of endoscopic surgical procedures.

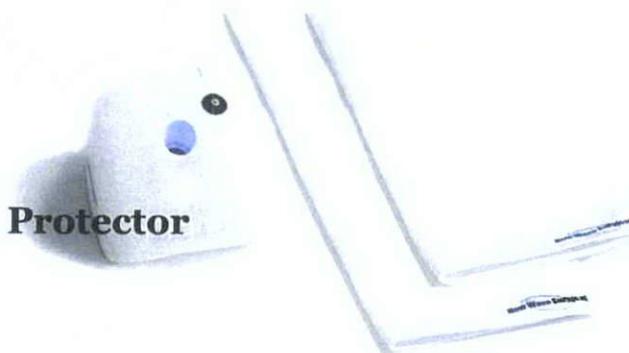
⑦ Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

The descriptive information contained in this 510(k) Notification is sufficiently precise to ensure the substantial equivalence of the Clear-Vu System to the predicate devices in terms of safety and effectiveness without the need for performance data, as the effect of the device (cleaned and defogged lens) is easily demonstrated. We believe the descriptive data provided in this 510(k) Notification are sufficient to support a substantial equivalence determination by FDA.

In conclusion, the Clear-Vu System is substantially equivalent to a combination of predicate devices, and the technological differences between the Clear-Vu System and the cited predicate devices are not significant in terms of safety or effectiveness.

D-H.E.L.P

Defogging Heated Endoscopic Lens Protector



D-HELP is a revolutionary multifunctional tool for laparoscopy that completely eliminates the fog problem, white balances the scope, cleans the scope, protects the scope and eliminates the fire and burn hazard during laparoscopy.

D-HELP is not just another defogger!

How will DHELP benefit your institution?

Reduce Costs:

- Eliminate the costs of antifog solutions and heated water
- Eliminate the costs of sterilizing the thermos and purchasing disposable seals.
- Prevent damage resulting from placing laparoscopes upside down in containers.
- Prevent damage caused by bathing the scope in hot saline instead of hot water.

Increase Efficiency and Safety:

- Reduce procedure operative time by improving visualization.
- Save valuable Circulator time by expediting the white balancing step and eliminating the need to place the light on standby every time the scope is removed from the body.
- Prevent the burn hazard associated with the fiber optic light.
- Prevent scratches and reduce cleaning time by using microfiber on the delicate lens.

Gain a Competitive Advantage Over Other Institutions:

- By offering your surgeons DHELP in their laparoscopies, you will improve their overall satisfaction during the procedure.
- Surgeons who have used DHELP have reported that they would prefer to schedule laparoscopies in hospitals that provide DHELP over hospitals that do not.

Product Features:

Defog with the combination of heat and anti-fog solution

Clean the lens properly with microfiber

White Balance correctly with a Tru-White® target

Protect the scope and eliminate the fire and burn hazard

Packaging:

Box of 10 individually packaged units

Each unit includes (1) DHELP and (2) MicroPads

- Once activated, DHELP functions 4-5 hours
- MicroPads are X-Ray Detectable
- DHELP is disposable. Do not resterilize.
- Gamma Sterilized
- Manufactured in an ISO 9001/13485 Certified facility
- FDA 510K #K062779



Product ID	Scope diameter	Scope angles	Scope manufacturers	Scope types
DHELP	5mm+10mm	All angles	All Brands	Rigid scopes only

New Wave Surgical
Suite 616
97-45 Queens Blvd.
Rego Park, NY 11374

SALES@NEWWAVESURGICAL.COM
WWW.NEWWAVESURGICAL.COM
PHONE:1-866-346-8883 Ext.5
FAX:1-866-586-6793



Medtronic

XOMED

Endo-Scrub[®] 2 Lens Cleaning System



Your clear advantage

Endo-Scrub® 2 Lens Cleaning System

Years of experience have allowed us to design the smartest lens cleaning system ever.

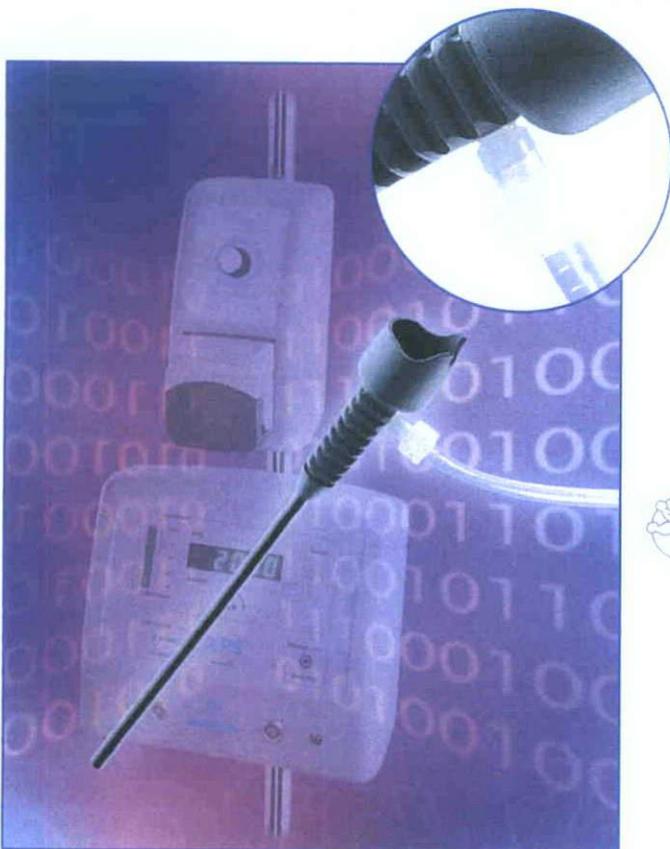
An advanced, software driven Endo-Scrub 2 System automatically adjusts forward and reverse flow for a superiorly clean lens with a tap of the footswitch.

With our SmartCycle Software™, we deliver the clearest view possible.

Six cycle settings allow you to custom-tune performance to your manufacturer's scope. A software-controlled "auto-purge" feature prohibits drips or air bubbles from forming over the lens by automatically voiding the sheath of residual air or fluid.

Now easier set-up and switching between scopes.

Pump head design allows faster loading and removal of tubing between cases, while the F-Z TWIST™ tubing connector makes switching between scopes a breeze. And the Endo-Scrub 2 is powered by our XPS 2000 console, no batteries or power cords needed!



Ordering Information

Endo-Scrub 2 System components		Qty
19-91005	Endo-Scrub 2 Pump Only	1 ea
19-91005U	Endo-Scrub 2 to Endo-Scrub 2 Pump Upgrade	1 ea
18-52000	Endo-Scrub 2 Footswitch	1 ea
19-91015	Endo-Scrub 2 Fingerswitch	1 ea

Endo-Scrub 2 Power Cord options		Qty
19-91019	Endo-Scrub 2 to XPS 2000 Console and Irrigator 7' Cable	1 ea
18-95505	Endo-Scrub 2 to XPS 2000 Console Cable - 2 ft	1 ea
18-95506	Endo-Scrub 2 to XPS 1 Console Cable - 8 ft	1 ea
19-91021	North America 110 VAC Power Cord	1 ea

Endo-Scrub 2 Sheaths

Endo-Scrub 2 Sheaths, 2.7mm		Qty
19-12021	Medtronic Xomed SharpSite Ar	5/box
19-12024	Smith Nephew I-ET	5/box
19-12027	Medtronic Xomed SharpSite Ar	5/box
19-12028	Smith Nephew I-ET	5/box

Endo-Scrub 2 Sheaths, 4.0mm		Qty
19-12000	Karl Storz Limatos Medtronic Xomed SharpSite Ar	5/box
19-12002	Storz Medtronic Xomed SharpSite Ar	5/box
19-12004	Smith Nephew I-ET	5/box
19-12006	Richard Wolfe	5/box
19-12032	Olympus	5/box
19-12018	Richard Wolfe (cat# 8475-32)	5/box
19-12019	Richard Wolfe (cat# 8885-433, 8880-433)	5/box
19-12010	Karl Storz Limatos	5/box
19-12011	Storz Medtronic Xomed SharpSite Ar	5/box
19-12012	Smith Nephew I-ET	5/box
19-12031	Olympus	5/box
19-12013	Karl Storz	5/box
19-12015	Medtronic Xomed SharpSite Ar	5/box
19-12020	Karl Storz Limatos Medtronic Xomed SharpSite Ar	5/box
19-12030	Endo-Scrub 2 Tubing Set	5/box

Note: All U.S. sheath lengths and soft tubing tubing may be purchased separately if a U.S. sheath is not being used.



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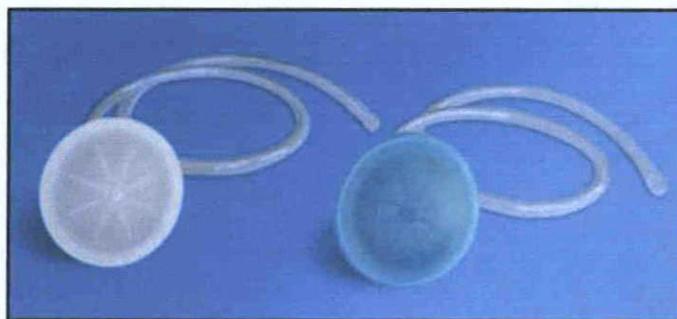
Medtronic USA, Inc.
6743 Southpoint Drive, North
Jacksonville, FL 32211
USA
Internet: www.xomed.com
Telephone: (800) 874-5191
Fax: (800) 678-1995

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Canada: 800 212 1617
China: 86 21 50800998
France: 33 470 679800
Germany: 49 233 253246
India: 91 22 26836733
Japan: 81 64 756 1500
UK: 44 1923 212233
USA: 854 296 9600

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Laparoscopic Smoke Evacuation Systems



SeeClear™ Plus™ & SeeClear™ MAX™

The SeeClear™ Plus™ and MAX™ are patented* multi-stage filter systems. They provide continuous, automatic clearance of smoke, bioaerosols and mist during laparoscopic procedures - without loss of pneumoperitoneum.

Simply attach the SeeClear™ filter system to an opened side port of a trocar. Surgical plume generated within the peritoneal cavity is pushed out by the elevated intraperitoneal pressure. No suction is required. Biocontaminants are captured. CO₂ is deodorized and returned to ambient air.

KEY BENEFITS:

- **Improve visual clarity** – Continuously clear away smoke, bioaerosols and mist from the field of view.
- **Reduce procedure time** – Eliminate the need to remove the laparoscope to clean the lens or to wait for the surgical plume to clear.
- **Prevent medical staff exposure to surgical plume** generated during laparoscopic procedures.

* U.S. Patents: 6,110,259; 6,589,316 B1 & 6,881,236 B2; EP Patent 1039961; Patents Pending



Product Specifications

Both SeeClear™ Models

Connector:	Acrylic Standard Luer; I.D. 0.146" - 0.169"
Tubing:	30" length, PVC, 0.25" I.D. / 0.375" O.D.
Filter Casing:	Medical Grade Polypropylene
Filter Materials:	Deodorization -- activated charcoal Filtration -- ULPA Grade Hydrophobic Glass Microfiber Efficiency -- 99.99% of 0.1 micron particles

Latex Free

Single Use Only

SeeClear™Plus™ – Model No. SC042500

Maximum flow rate: 4.0 Liters/minute at a 15mmHg pressure differential; clear colored filter.

Recommended use: With a 10mm trocar if a lower flow rate insufflator is being used.

SeeClear™MAX™ – Model No. SC062500

Maximum flow rate: 6.0 Liters/minute at a 15mmHg pressure differential; green colored filter.

Recommended use: a) With a 5mm trocar; or b) With a 10mm trocar if maximum smoke clearance is desired.

Rev 070110

JLJ Medical Devices International, LLC

Internet: www.jljmedicaldevices.com
6585 Edenvale Blvd., Suite 150
Eden Prairie, MN 55346
telephone 952.929.3881 facsimile 952.929.3984



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. William J. Post
Chief Executive Officer
Minimally Invasive Devices, LLC
1275 Kinnear Road
COLUMBUS OH 43212

NOV 30 2007

Re: C070324
Device Name: MID Clear-Vu System
Dated: October 8, 2007
Received: October 11, 2007

Dear Mr. Post:

We have reviewed the above referenced request for information, submitted in accordance with Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act), regarding the regulatory requirements applicable to the MID Clear-Vu System. Based on the information provided in your submission, we believe that the MID Clear-Vu System falls within Title 21 of the Code of Federal Regulations (CFR) 876.1500(b)(1), Endoscope and accessories. An Endoscope and its accessories, under 21 CFR 876.1500(b)(1), are Class II type devices. Therefore, you will need to submit a premarket notification [510(k)] and receive the Food and Drug Administration's (FDA's) clearance prior to marketing your device. You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act.

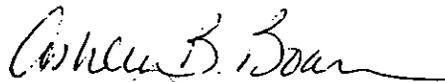
Please be advised that Title 21 Code of Federal Regulations, Part 807, Subparts A-D, requires all establishments, whether foreign or domestic, that are engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into or distribution in the U.S. to register and list with the FDA. If you have any questions regarding the registration and listing requirements, please call 240-276-0132.

Section 513(g) of the Act requires the agency to provide information about the regulatory requirements applicable to a particular type of device. The response represents my best judgment about how the product would be regulated, based upon our review of the information you have provided, including your description of the product and its intended use. My response to a 513(g) request is not a classification decision for a device and does not constitute FDA clearance or approval for commercial distribution.

Page 2 – Mr. William J. Post

If you have any questions regarding this letter, please contact Ms. Janine Morris, Chief, Urology and Lithotripsy Devices Branch, at (240) 276-4161 or for general questions please contact the Division of Small Manufacturers International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for Donna-Bea Tillman, Ph. D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

MID
LLC

K080613

CLEAR-VU
SYSTEM



COVER SHEET MEMORANDUM

From: Reviewer Name VRao NIMMAGADDA
 Subject: 510(k) Number K080613/S²
 To: The Record

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%20202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		NA
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank</i> ? (If not, then applicant must be contacted to obtain completed form.)			✓ ✓ NA
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			✓
Nanotechnology			✓

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.	<input checked="" type="checkbox"/>
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	<input checked="" type="checkbox"/>

Regulation Number 21 CFR 876.1500 Class* II Product Code K06

Additional Product Codes: GCT (*If unclassified, see 510(k) Staff)

Review: [Signature] ULDB 11/04/2008
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 11/6/08
(Division Director) (Date)



Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K080613/S002

Date: November 4, 2008
To: The Record
From: Rao Nimmagadda

Office: ODE
Division: DRARD

510(k) Holder: Minimally Invasive Devices, LLC
Device Name: Clear-Vu™ System
Contact: Michael H. Southworth, RAC
Phone: (216) 287-0312
Fax: (330) 425-2147
Email: sa_consulting@hotmail.com

I. Purpose and Submission Summary

(b)(4) Trade Secret Process - Product Specs



Clinical Consult

(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Prescription Device)	x		
Truthful and Accuracy Statement	x		
510(k) Summary or 510(k) Statement	x		
Standards Form	x		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?		x	
Is the device sterile?	x		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		x	

The Clear-Vu™ System consists of a multi-lumen sheath assembly mounted on the shaft of a laparoscope with standard tubing connecting the device to the existing CO₂ insufflation circuit and the existing surgical irrigation system. Specifically, the Clear-Vu System consists of: 1) a Sheath Assembly for laparoscopes with 0°, 30° or 45° angled tips; 2) a Handle Assembly; and 3) Tubing and Connectors, including a connector to the insufflator, a water spike to the pressurized saline, and a connector to the trocar. Pictures of the device are presented in Figures 2-6 under Tab 9 (original submission).

(b)(4) Trade Secret Process - Product Specs

IV. Indications for Use

Clear-Vu is a single-use, disposable laparoscopic accessory device that is intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while

maintaining visualization of the surgical site.

V. Predicate Device Comparison

This information is provided under Tab 13 in the original submission.

Clear-Vu System is claimed to be substantially equivalent to the combination of the following legally marketed devices in terms of safety and effectiveness:

Defogging Heated Endoscope Lens Protector (D.H.E.L.P.)/New Wave Surgical Corp/K062779

Endo-Scrub® 2 Lens Cleaning System/Xomed,Inc./K982594

See Clear Laparoscopic Smoke Evacuation System/JLJ Medical Devices International, LLC/510(k) Exempt

The Clear-Vu System has more in common with the D.H.E.L.P. than with other devices.

VI. Labeling

Labeling, including the Proposed Instructions for Use and Promotional Information are provided under Tab 10 in the original submission. (b)(4) Trade Secret Process - Product Specs

[Redacted]

(b)(4) Trade Secret Process - Product Specs

[Large redacted area]

VII. Sterilization/Shelf Life/Reuse

(b)(4) Trade Secret Process - Product Specs

[Large redacted area]

(b)(4) Trade Secret Process - Product Specs

VIII. Biocompatibility

The required biocompatibility tests were conducted. There are no biocompatibility issues.

IX. Software No Software

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable.

XI. Performance Testing – Bench

(b)(4) Trade Secret Process - Product Specs

XII. Performance Testing – Animal

(b)(4) Trade Secret Process - Product Specs

XII. Performance Testing – Clinical No clinical testing was required.

XIII. Substantial Equivalence Discussion

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

Note: See

http://erom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

3. Describe the new technological characteristics:

(b)(4) Trade Secret Process - Product Specs



4. Explain how new characteristics could or could not affect safety or effectiveness:

(b)(4) Trade Secret Process - Product Specs



6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

(b)(4) Trade Secret Process - Product Specs



8. Explain what performance data is needed:

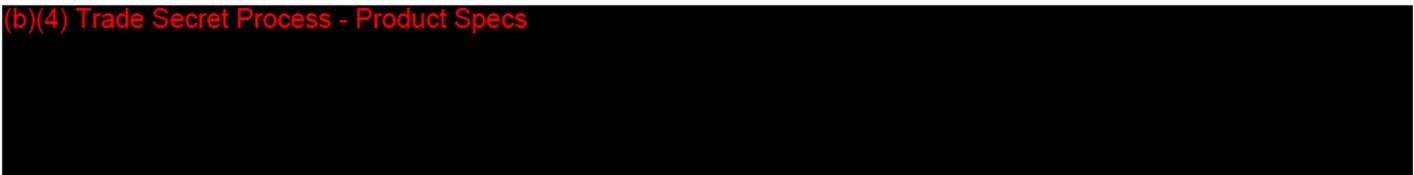
(b)(4) Trade Secret Process - Product Specs



9.

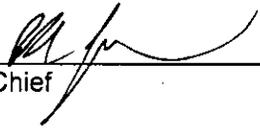
XIV. Recommendation

(b)(4) Trade Secret Process - Product Specs



Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope Accessory
Regulatory Class: Class II
Product Code: KOG, GCJ

VRao Nimmagadda
Reviewer


Branch Chief
Acting

November 4, 2008
Date

11/04/2008
Date



Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K080613

Date: April 28, 2008
To: The Record
From: Rao Nimmagadda

Office: ODE
Division: DRARD

510(k) Holder: Minimally Invasive Devices, LLC
Device Name: Clear-Vu™ System
Contact: Michael H. Southworth, RAC
Phone: (216) 287-0312
Fax: (330) 425-2147
Email: sa_consulting@hotmail.com

I. Purpose and Submission Summary

(b)(4) Trade Secret Process - Product Specs

II. Administrative Requirements

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

III. Device Description

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

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

The Clear-Vu™ System consists of a multi-lumen sheath assembly mounted on the shaft of a laparoscope with standard tubing connecting the device to the existing CO₂ insufflation circuit and the existing surgical irrigation system. Specifically, the Clear-Vu System consists of: 1) a Sheath Assembly for laparoscopes with 0°, 30° or 45° angled tips; 2) a Handle Assembly; and 3) Tubing and Connectors, including a connector to the insufflator, a water spike to the pressurized saline, and a connector to the trocar. Pictures of the device are presented in Figures 2-6 under Tab 9.

(b)(4) Trade Secret Process - Product Specs

IV. Indications for Use

Clear-Vu is a single-use, disposable laparoscopic accessory device that is intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site.

V. Predicate Device Comparison

This information is provided under Tab 13.

Clear-Vu System is claimed to be substantially equivalent to the combination of the following legally marketed devices in terms of safety and effectiveness:

Defogging Heated Endoscope Lens Protector (D.H.E.L.P.)/New Wave Surgical Corp/K062779

Endo-Scrub® 2 Lens Cleaning System/Xomed, Inc./K982594

See Clear Laparoscopic Smoke Evacuation System/JLJ Medical Devices International, LLC/510(k) Exempt

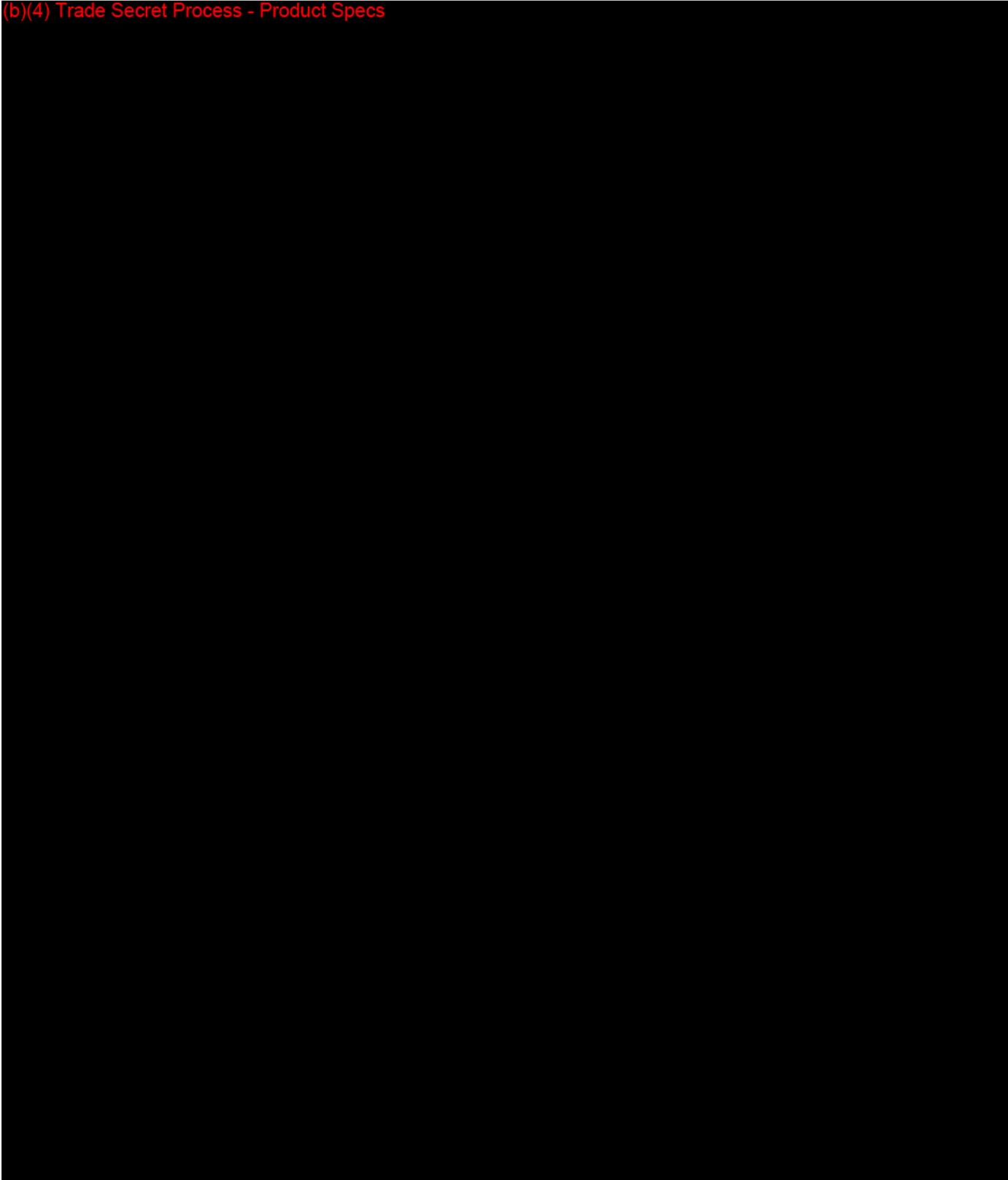
The Clear-Vu System has more in common with the D.H.E.L.P. than with other devices.

VI. Labeling

Labeling, including the Proposed Instructions for Use and Promotional Information are provided under Tab 10.

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VII. Sterilization/Shelf Life/Reuse

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VIII. Biocompatibility

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IX. Software No Software

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable.

XI. Performance Testing – Bench

No bench testing provided. (b)(4) Trade Secret Process - Product Specs

XII. Performance Testing – Animal

No animal testing provided. (b)(4) Trade Secret Process -

P d t S

XIII. Performance Testing – Clinical

XIV. Substantial Equivalence Discussion

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

Note: See

http://erom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

3. Describe the new technological characteristics:

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4. Explain how new characteristics could or could not affect safety or effectiveness:

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6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

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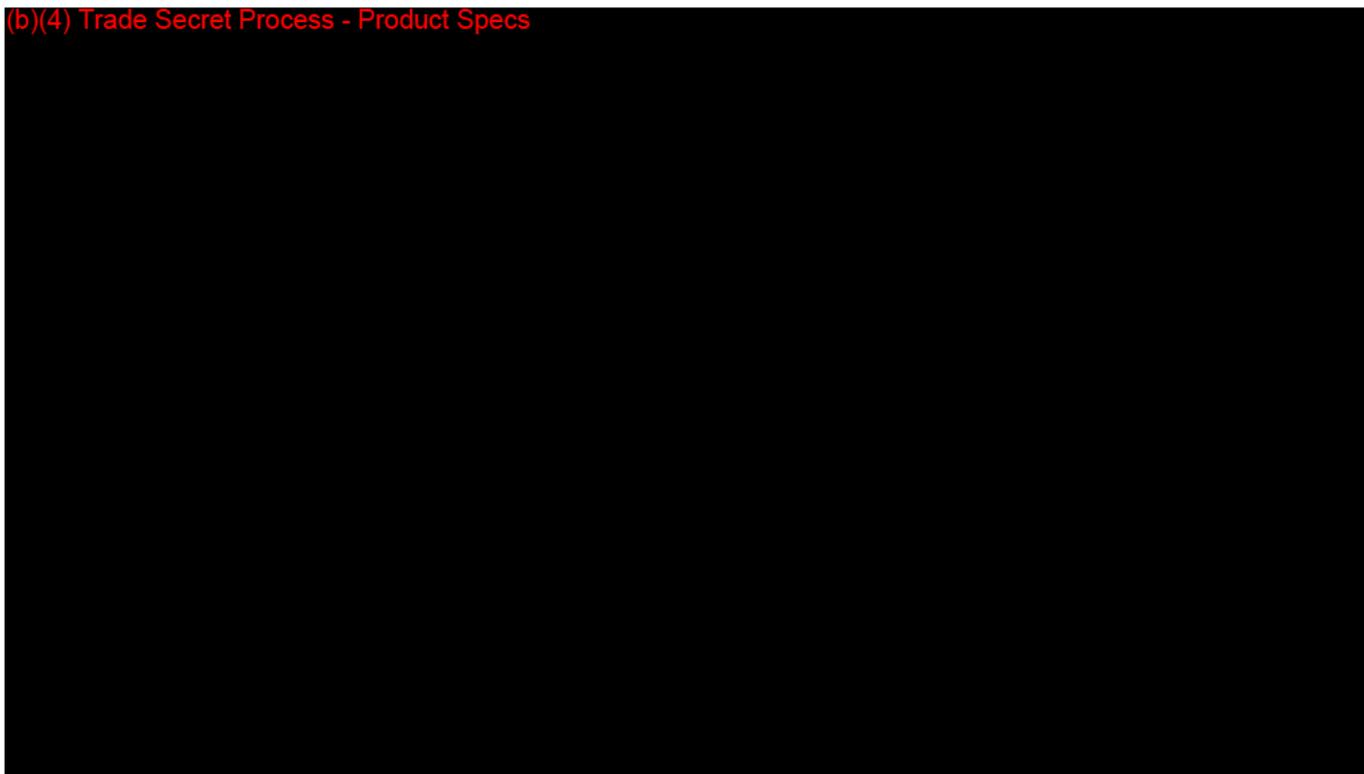


8. Explain what performance data is needed:

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XVI. Contact History

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XVII. Recommendation

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Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope Accessory
Regulatory Class: Class II
Product Code: KOG, GCJ

V Rao Nimmagadda
Reviewer
(ACTING) James P. Seher
Branch Chief

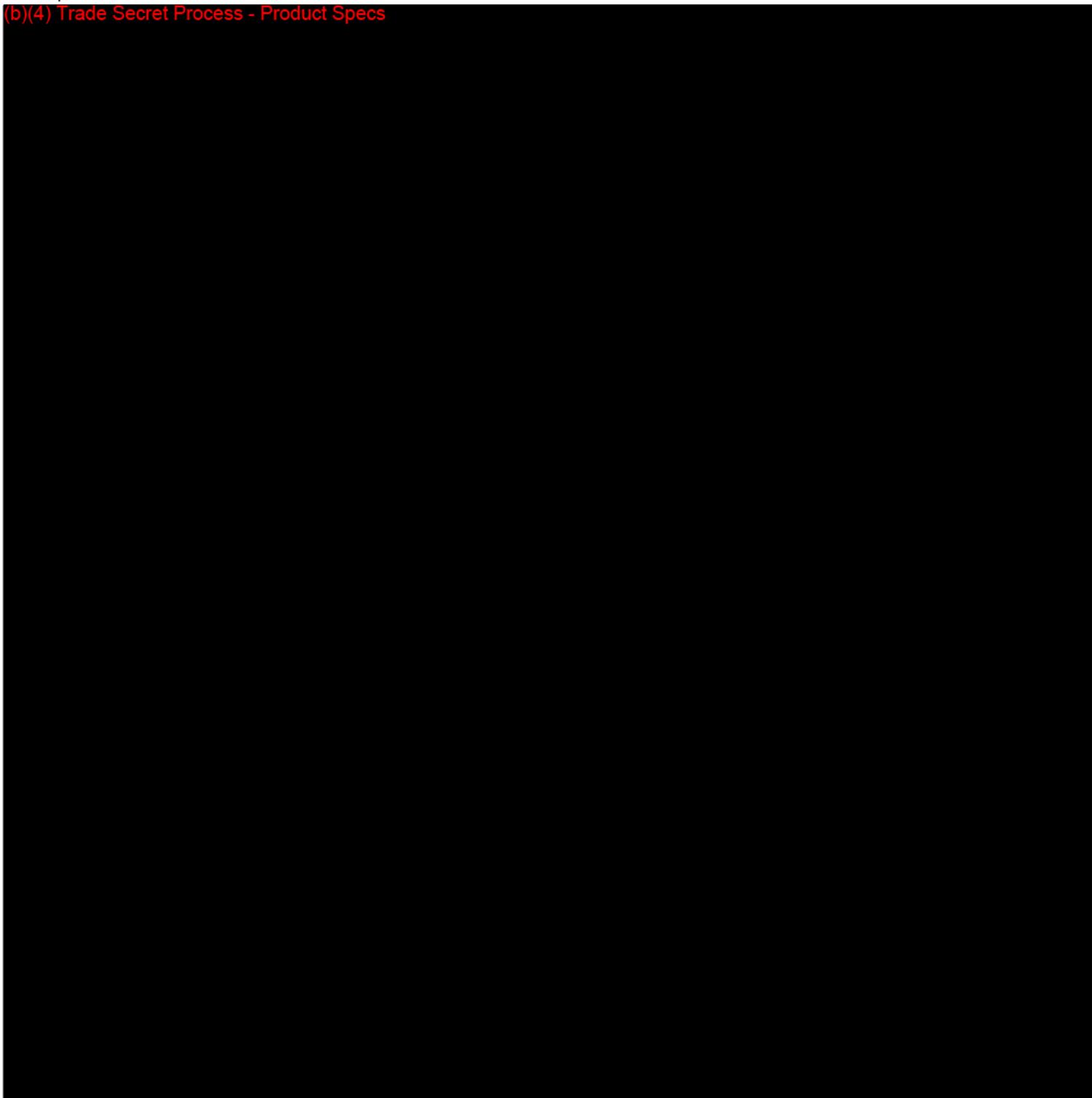
April 28, 2008
Date
4/29/08
Date

Nimmagadda, Venkatrao

From: Nimmagadda, Venkatrao
Sent: Monday, April 28, 2008 5:47 PM
To: 'sa_consulting@hotmail.com'
Cc: Nimmagadda, Venkatrao
Subject: (b)(4) Trade Secret Process - Product Specs

Dear Mr. Souhworth:

(b)(4) Trade Secret Process - Product Specs



Venkatrao Nimmagadda, Ph.D.

Chemist, Urology and Lithotripsy Devices Branch (ULDB)
Division of Abdominal, Reproductive and Radiological Devices (DRARD)
Office of Device Evaluation (ODE)
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration (FDA)
9200 Corporate Blvd, HFZ-470
Rockville, Maryland 20850

(240) 276-4134 (Phone)

(240) 276-4156 (Fax)

venkatrao.nimmagadda@fda.hhs.gov

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COVER SHEET MEMORANDUM

From: Reviewer Name _____
Subject: 510(k) Number K080613
To: The Record

- Please list CTS decision code _____
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/Screening Checklist](http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ScreeningChecklist))
 - Hold (Additional Information or Telephone Hold):
 - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU.		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III? If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABB_REVIATED_STANDARDS_DATA_FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Is clinical data necessary to support the review of this 510(k)?			
Does this device include an Animal Tissue Source?			✓
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		✓

Regulation Number _____ Class* _____ Product Code _____
 (*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____
 (Branch Chief) (Branch Code) (Date)

Final Review: _____
 (Division Director) (Date)

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2, or 3; do NOT begin the review of this 510(k):		YES	NO
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see <u>H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC</u>)			✓
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?)			✓
3. Does this device type require a PMA by regulation? (Please see management.)			✓
Questions 4-8 are intended to help you start your review:		YES	NO
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)			✓
5. a. Did the firm request expedited review? (See management,) b. Was expedited review granted? (See <i>Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions</i> , http://www.fda.gov/cdrh/mdufma/guidance/108.html)			✓
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here: C070324	✓	
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:		✓
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see <i>Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission</i> http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			

Southworth & Associates

Medical Device Regulatory Affairs & Compliance

K080613/S2

FDA CDRH DMC

OCT 30 2008

Received

CONFIDENTIAL

October 28, 2008

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

Handwritten initials: KD

**Attn: 510(k) Document Mail Center
Venkatrao Nimmagadda, Ph.D., DRARD/ULDB**

Re: K080613/S2, Clear-Vu™ System, Minimally Invasive Devices, LLC

Dear Dr. Nimmagadda:

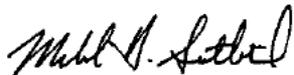
(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



Sincerely,



Michael H. Southworth, RAC
Principal & Senior Consultant
Southworth & Associates, LLC

cc: Wayne L. Poll, MD, Chairman
Minimally Invasive Devices, LLC

510(k) Summary of Safety and Effectiveness
Clear-Vu System
Minimally Invasive Devices, LLC

510(k) Submitter	Minimally Invasive Devices, LLC 1275 Kinnear Road Columbus, Ohio 43212
Contact Person	Wayne L. Poll, MD, Chairman <i>Phone:</i> (614) 580-2022 <i>Fax:</i> (614) 889-7630 <i>E-mail:</i> waynepoll@hotmail.com
Date Prepared	Revised October 28, 2008
Device Name	<i>Proprietary Name:</i> Clear-Vu System <i>Common Name:</i> endoscope lens cleaning and defogging device <i>Classification Name:</i> "accessory, endoscope," a class II device in accordance with 21 CFR § 876.1500
Intended Use	The Clear-Vu System is a single-use, disposable laparoscopic accessory device intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site.
Device Description	The Clear-Vu System consists of a multi-lumen sheath assembly mounted on the shaft of the laparoscope, which connects to the existing CO ₂ insufflation circuit to defog the laparoscope lens and divert surgical debris, and connects to the existing surgical irrigation system to clean the lens via saline flush.
Substantial Equivalence	The Clear-Vu System is substantially equivalent in terms of safety and effectiveness to the following predicate devices: <ol style="list-style-type: none">1. Defogging Heated Endoscopic Lens Protector / K062779 New Wave Surgical Corp.2. Endo-Scrub® 2 / K982594 Xomed, Inc.3. SeeClear™ Laparoscopic Smoke Evacuation System/510(k) Exempt JLJ Medical Devices International, LLC
Technological Comparison	The Clear-Vu System is substantially equivalent to the cited predicate devices in terms of intended use, and the technological differences are not significant relative to the safety or effectiveness of the new device.
Performance Testing-Bench	The device was subjected to simulated use testing to demonstrate its effectiveness in a surgical environment simulation chamber.
Performance Testing-Animal	The device was subjected to preclinical animal testing to demonstrate its effectiveness in a porcine model.