U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(ldt)
FOLDER:	K933094 - 35 pages
COMPANY:	INMAN MEDICAL CORP. (INMAMEDI)
PRODUCT:	INSUFFLATOR, LAPAROSCOPIC (HIF)
SUMMARY:	Product: INSUFFLATOR TUBING KIT W/FILTER
DATE REQUESTED:	Oct 8, 2014
DATE PRINTED:	Oct 8, 2014
Note:	Printed

APR 18 1994

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Ms. Pam Liberto
Director of Quality
Inman Medical Corporation
6316 Airport Freeway
Fort Worth, Texas 76117

Re: K933094
Laparoscopic Insufflator Tubing Kit with Filter
Dated: June 17, 1993
Received: June 24, 1993
Regulatory Class: II
21 CFR 884.1730

Dear Ms. Liberto:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). General controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation ou might have under the Radiation Control for Health and Safety Act of 1968, r other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence for your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326), at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

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

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date

From REVIEWER(S) - NAME(S) Yung Pak

Subject 510(k) NOTIFICATION K933094

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

☑ (A) Is substantially equivalent to marketed devices. Tier-1

☐ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

☐ (C) Requires more data.

☐ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☑

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☑ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

☑ No Confidentiality

☐ Confidentiality for 90 days

☐ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

85HIF, class II, 21CFR 889.1730

Additional Product Code(s) w/Panel (optional):

REVIEW: Colin M Pollard (BRANCH CHIEF) | OGDB (BRANCH CODE) | 4/15/94 (DATE)

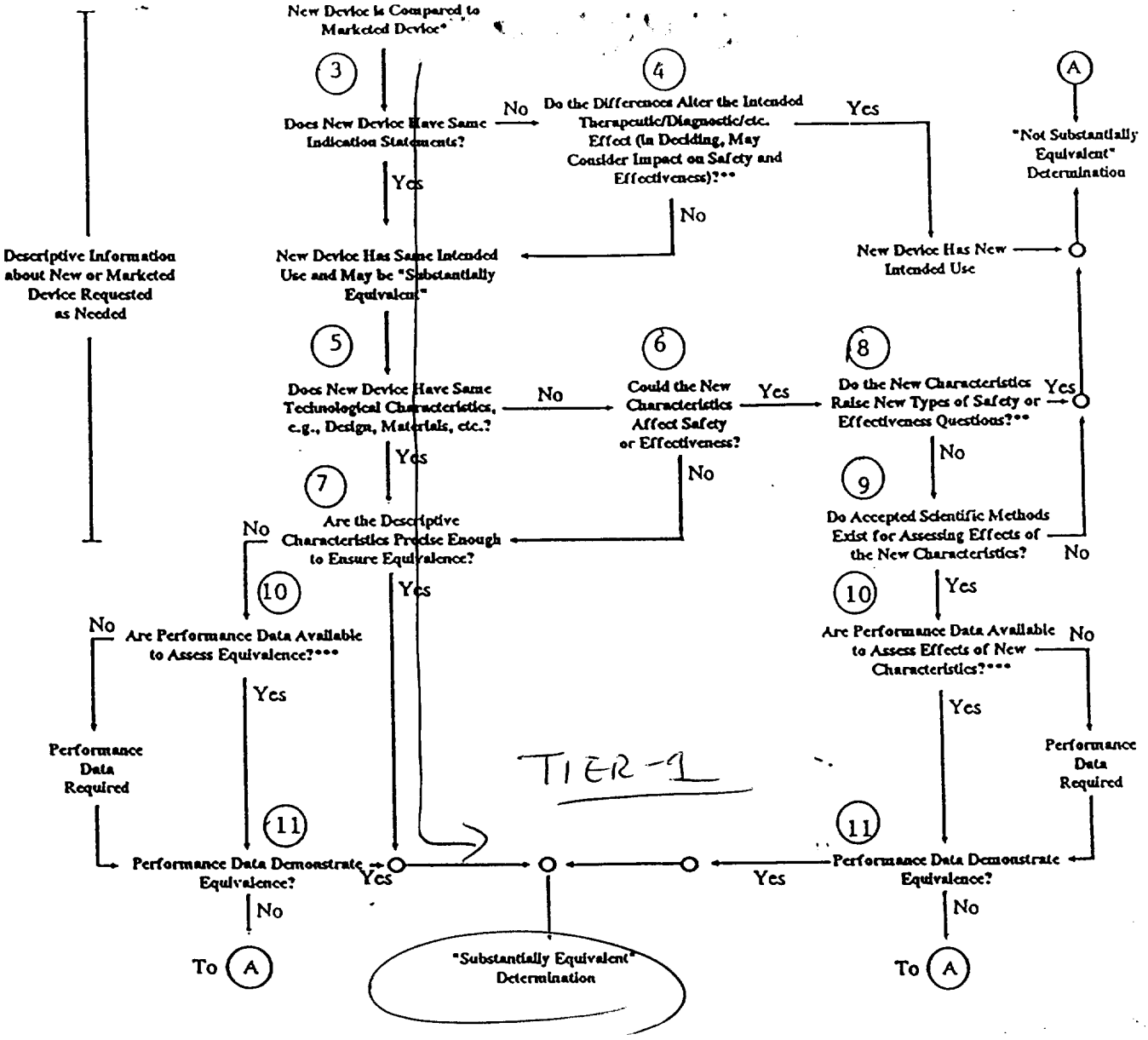
FINAL REVIEW: R Cathins for CYir (DIVISION DIRECTOR) 4/15/94 (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

2

Revised 11/18/91

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



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

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

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

DRAERD'S TRIAGE/TIER 1 PILOT PROGRAM
REVIEW CHECKLIST

510(k) NUMBER K933094

CFR NO. 884.1730 (COMPLETE ONLY IF SE)

YES OR NO

Yes 1. MANUFACTURER HAS COMPLETED ALL PARTS OF "MANUFACTURER'S STATEMENT OF SUBSTANTIAL EQUIVALENCE" AND HAS SIGNED FORM.

Yes 2. INDICATIONS FOR USE, LABELING, AND ALL CLAIMS ARE CONSISTENT WITH PREAMENDMENT OR LEGALLY MARKETED DEVICES.

N/A 3. IF DRAERD REQUIRES CONFORMANCE TO VOLUNTARY OR MANDATORY STANDARDS FOR THIS DEVICE, THE MANUFACTURER HAS SUBMITTED CERTIFICATION.

IF ALL CHECKS ARE "Y", THEN 510(K) IS SUBSTANTIALLY EQUIVALENT TO THE PREDICATE DEVICE. IF ONE ANSWER IS NO, THEN 510(K) MUST UNDERGO TIER 2 REVIEW.

N/A OPTIONAL SPOT CHECK TIER 2 REVIEW. (WRITTEN REVIEW ATTACHED.)

REVIEWER'S NAME Yung Pak

DATE 3/25/94

(ODE/DRAERD/PJM/LLY//DAS: 1/4/94)
(PJM 3½ disc A:\TIER1CHK)

TIER-1

K933094

Reviewer: Yung Pak
Mechanical Engineer

Division/Branch: DRAERD/ADOU/OGDB (HFZ-470)

Trade Name: Insufflator Tubing Kit w/Filter

Common Name: Insufflator Tubing Kit w/Filter

Manufacturer: Inman Medical Corp.
6316 Airport Freeway
Forth Foth, TX 76117
Contact: Pam Liberto
1-800-553-8523

Product to which compared: **Tier-1**

DEVICE DESCRIPTION

1. **Intended Use:**

To transfer and filter CO_2 gas from insufflator to a patient's peritoneal cavity during laparoscopic procedure.

2. **Device Description:**

The device is sterile, disposable, single-use insufflation tubing with built-in filter. The tubing is 10 ft. long and made of clear PVC. It has rotating male luer lock (MLL) at each end and a 0.2 um filter to filter out the particulates from external CO_2 source.

3. **Labeling:**

I have reviewed the labeling and it meets the requirement.

5

4. Substantial Equivalence (SE) Decision Making Documentation

	YES	NO	
1. IS PRODUCT A DEVICE?	x	___	IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	x	___	IF NO STOP
3. SAME INDICATION STATEMENT?	x	___	IF YES GO TO 5
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?	___	___	IF YES STOP -> NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?	x*	___	IF YES GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?	___	___	IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	x*	___	IF YES STOP -> (SE)

*** per the manufacturer's Tier-1 certification statement**

RECOMMENDATION: Substantially Equivalent - Tier 1 policy

ProCode: 85 HIF
Class: II
CFR #: 21 CFR §884.1730

Yung Pak 3/24/94
Yung Pak Date

Chief, Ob-Gyn Branch Date

/√/ Concur

/ / Do Not Concur; Comments:

6

IMC

4-6-94

To: Yung Pak

RE: 510(K) K933094 Insufflator Tubing Set w/ Filter

Following are the label changes we will be making.

IMC

INSUFFLATOR TUBING SET

10 FEET LONG WITH
.2 MICRON EFFECTIVE FILTER
AND MALE LUER LOCK CONNECTORS

Laparoscopic

INTENDED FOR ONE TIME USE

(Not for Hysteroscopic Use)

REORDER NO.

1050

STERILE: Contents Sterile Unless Package is Opened or Damaged.	QTY. Lot No.

Caution: federal law restricts this device to sale on the order of a physician

~~WARNING: THIS DEVICE TO BE USED BY OR UNDER THE DIRECTION OF A PHYSICIAN.~~

INMAN MEDICAL CORP.
6316 Airport Freeway
Fort Worth, Texas 76117
(817) 831-2462 • (800) 553-8523

INMAN MEDICAL CC

RMC LAB0285 • 817-831-4700

IMC

MARCH 15, 1994

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL (HFZ-401)
1390 PICCARD DRIVE
ROCKVILLE, MD 20850

ATTN. YUNG PAK

RE; 510(k) K933094 INSUFFLATOR TUBING SET W/ FILTER

AS YOU REQUESTED, THE LENGTH OF THE TUBING IS 10 FEET.

CONTACT ME IF YOU SHOULD HAVE ADDTIONAL QUESTIONS.

SINCERELY,

Pam Liberto

PAM LIBERTO
RA/QA MANAGER

8

INMAN MEDICAL CORP. • 6316 Airport Freeway • Fort Worth, Texas 76117 • 817-831-4700

IMC

February 16, 1994

Food & Drug Administration
Center for Devices and Radiological Health
Document Mail (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

RE: Triage Program - Tier 1 Product
510(k) K933094

Dear Sir/Madam:

Enclosed is the information that Ms. P. Miller had requested under the new Triage Program.

Please contact me if you should have any questions at 800-553-8523.

Sincerely,

Pam Liberto

Pam Liberto
QA/RA Manager

Encl.

fdatriag.sam

INMAN MEDICAL CORP. • 6316 Airport Freeway • Fort Worth, Texas 76117 • 817-831-4700

MANUFACTURER'S STATEMENT OF SUBSTANTIAL EQUIVALENCE

(To be provided with 510(k) notifications for tier 1 devices)

STATEMENT OF INDICATIONS FOR USE: This Insufflator Tubing Set pre-conditions carbon dioxide for a safer pneuoperiteum for all laparoscopic procedures.

CLAIMS: Sterile gas filteration is achieved via the .2 micron filter trapping particulate matter.

Hydrophobic Filter creates barrier preventing back flow of body fluids minimizing the risk of cross-contamination.

This notification contains all of the information required by 21 CFR 807.87. A completed copy of the "DRAERD Premarket Notification 510(k) Reviewer's Screening Checklist" is attached.

The subject device conforms to the following voluntary and mandatory standards:

-NONE

The subject device has the same technological characteristics as a legally marketed predicate device. Specifically, the features, specifications, materials, and mode of action are equivalent. If the subject device is a kit, all of the contents of the kit are either pre-Amendment devices or have been cleared for marketing through previous 510(k)s. The kit contains no drug or biologic product.

The above statements are accurate representations of this 510(k) premarket notification and of the device this firm intends to market. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted (21 CFR 807.87(j)).

MANUFACTURER: INMAN MEDICAL CORPORATION

OFFICIAL CORRESPONDENT: Pam Liberto (signature)

Pam Liberto (printed name)

TITLE: QA/RA Manager

DATE: 2/16/94

10

RRG/LLD 1/6/93
Rev. 9/24/93

DRAERD Premarket Notification 510(k)
Reviewer's Screening Checklist

510(k) Number & Device Name K933094 Insufflator Tubing Kit w/Filter

Company INMAN MEDICAL CORP.

ITEM	PRESENT Yes	PRESENT No	NEEDED (Y/N/?)
1. General information (i.e., trade & classification name, Est. Reg. No., device class, meets special controls or a performance standards, etc.)	✓	—	Y
Reason for 510(k) - new device or modification	✓	—	Y
Identification of legally marketed equivalent device	✓	—	Y
2. Proposed Labeling, Labels, Advertisements	✓	—	Y
Description of new device/modification	✓	—	Y
Intended use statement	✓	—	Y
Diagrams, Engineering Drawings, Photographs	✓	—	Y
3. Comparison of similarities/differences to named legally marketed equivalent device	✓	—	Y
Equivalent Device Labeling, Labels, Advertising	✓	—	Y
Intended use of equivalent device	✓	—	Y
4. List of all patient contacting materials in new device	✓	—	Y
Comparison of materials to equivalent device	✓	—	Y
5. Biocompatibility information/data for patient contacting materials, (OR)	—	—	—
Certification - identical material/formulation	✓	~~—~~ P. Libuch 5/19/94	Y
6. Performance data: Bench data	—	NA	—
Animal data	—	NA	—
Clinical data	—	—	—
7. Sterilization information	✓	—	Y
8. Software validation & verification	—	NA	—
9. 510(k) summary or (statement)	✓	—	Y
10. If Class III, Class III Certification & Summary	—	NA	—
11. If kit, kit certification	—	NA	—

RECEIVED
MAY 04 10
FDA/CDRH/ODE/DMC

11

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

JAN 28 1994

~~John Mayall~~ Pam Liberty
Director of Quality Assurance
and Regulatory Affairs
Inman Medical Corporation
6316 Airport Freeway
Fort Worth, Texas 76117

Re: K933094
Insufflator Tubing Kit with Filter
Dated: June 17, 1993
Received: June 25, 1993

Dear Mr. Mayall:

The Office of Device Evaluation (ODE) has undertaken several initiatives to streamline the process by which new medical devices can be reviewed and cleared for marketing, without subjecting the public to added risks. One of these initiatives is the Triage Program. The Triage Program entails the sorting of incoming 510(k) premarket notifications into three predetermined tiers, each of which is associated with differing levels of review effort. An anticipated benefit of the Triage Program is that the reduced review effort for tier-1 devices will result in abbreviated review times.

The ODE Division of Reproductive, Abdominal, Ear, Nose, Throat, and Radiological Devices (DRAERD) is now implementing a pilot approach to the Triage Program. A copy of the program is enclosed for your information.

An essential feature of the DRAERD Triage Program is a manufacturer's statement of substantial equivalence for tier-1 devices. We have conducted an administrative review of your 510(k) and have concluded that the device you intend to market is a tier-1 device. In accordance with the DRAERD Triage Program, we will conduct a limited review (limited to a review of the labeling), but you, the manufacturer, must provide certain statements.

To provide you an opportunity to complete the statements, thus permitting us to conduct a tier-1 review, we are setting aside your 510(k) until we receive a completed and signed copy of the "Manufacturer's Statement of Substantial Equivalence" (attached to the DRAERD Triage Program). We will not place your 510(k) on "hold" while waiting for your response; therefore, your place in the review queue will not suffer adversely.

If your device technological characteristics differ from those of legally marketed predicate devices, you will be unable to provide the statements necessary for tier-1 devices. If such is the case, please inform us of your conclusion and describe the differences, as required by 21 CFR 807.87. We will then proceed to review your 510(k) as a tier-2 or tier-3 device.

The additional information should be submitted in duplicate, referencing the 510(k) number above to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

12

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

If the requested information is not received within 30 days, we will place your 510(k) on "hold." If the requested information is not received within the subsequent 30 days (total of 60 days), we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after the second 30 days, it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, or comments or questions concerning this DRAERD Triage Program, please contact David Segerson at (301) 594-1212. If you need information or assistance concerning the IDE or other regulations or copies of guidance documents, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 628-2041 or at (301) 443-6597.

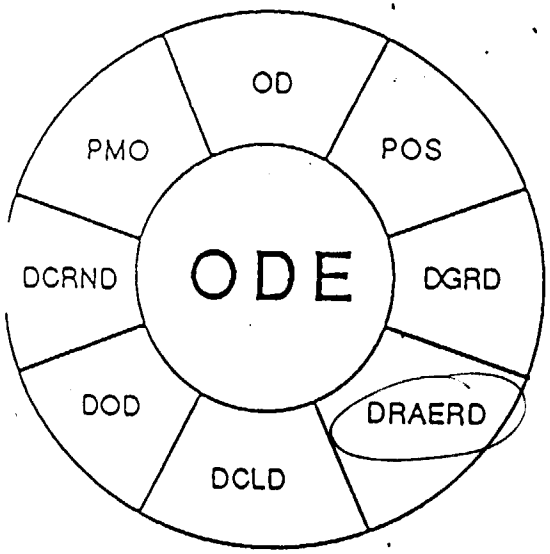
Sincerely yours,

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

Enclosure

13

Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices



DHHS/PHS/FDA/CDRH/ODE

1390 Piccard Drive
Rockville, MD 20850

Phone No.: (301) 594- 1212

Fax No.: (301) 594-2359

TO: Pam Liberto / Immom Med.

FROM: Dr. L. Yin

Comments: Triage / Trv I re: K 933054

No. of Pages: 3
(including cover sheet)

Please advise if transmission is illegible.

****
*** ACTIVITY REPORT ***
****

TRANSMISSION OK

TX/RX NO.	2707
CONNECTION TEL	918178312462
CONNECTION ID	
START TIME	01/28 09:59
USAGE TIME	01'57
PAGES	3
RESULT	OK

15

OST → ODE ROUTING FOR REVIEW DOCUMENTS

LR
Noted
1/24/94
RKL

OST DIVISION (CHECK ONE) DATE: 1/13/94

DECS	____	HFZ-140	TW 134	443-3314 x 26
DLS	____	HFZ-110	TRL 2B	443-7115
DMMS	____	HFZ-150	WIL 202	443-7003
DPS	✓	HFZ-130	TW7 742	443-6536

RAR

APPLICATION #	SE	AI	NSE	DISK	MEMO
IC933094		✓			✓

PR

OST/OD
HFZ-100 443-2444 TW 108
INITIAL: BKK DATE: 1/14

ODE/POS
HFZ-400 PHONE: 594-1190
INITIAL: DT DATE: 1/21/94

DGRD ____ DCLD ____ DRAERD ____ DOD ____ DCRND ____

ASSOCIATE DIVISION DIRECTOR: _____

HFZ-____ Phone: _____

160

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

Document Control Number: K933094
Login Date: 06/24/93
90 Day Due Date: 09/25/93

Reviewer: Ronald A. Robinson
443-6113 (HAB)
Division/Branch: DRAERD/OGDB

Applicant and Contact: Inman Medical Corp.
63116 Airport Freeway
Ft. Worth, TX76117
Contact: John Mayall
(817) 831-4700

Trade Name: Laparoscopic Insufflator Tubing Kit w/Filter
Common Name:Same

Product To Which Compared: O.R. Concepts, Roanoke, TX, K923818,K923909,K925147 and Marlow Surgical Technologies, Willoughby, OH Product #88-5050 (OTT Insufflator Tubing/Filter Kit.

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

See YUNG PAK's Review.

NARRATIVE DEVICE DESCRIPTION

1. Intended Use: This is a single use product supplied sterile. This device is intended for use during abdominal laparosscopic surgery.

2. Device Description: This device is a sterile insufflator Tubing w/filter kit. It consists of Medical grade PVC tubing (Natvar Part# 607 (K850506). It further consists of a Pall oxygenator gas line filter, Model # OR01, which has been marketed since prior to 1976 by Pall Biomedical Products Corp (see letter dated 3/17/93. Finally it consists of luer fittings from Qosina polycarbonate rotating luer fittings (K925147).These components are substantially equivalent to the components in the devices outlined in Exhibit #3 which are currently in commercial use.

	YES	NO
Is the device life-supporting or life sustaining?	___	X
Is the device implanted (short-term or long-term)?	___	X
Does the device design use software?	___	X
Is the device sterile?	___	X
Is the device single use?	X	___
Is the device home use?	___	___
Is the device for prescription?	___	___
Does the device contain a drug or biological product as a component?	___	X
Is this device a kit?	___	X

A. Device Description
Insufflator tubing w/filter kit

B. Device Materials and Toxicity
All components are stated to be substantially equivalent to predicate device or the kit includes prior approved components.

C. Physical Properites and Performance Testing
Stated to be substantially equivalent predicate devices.

18

Stated to be substantially equivalent predicate devices.

D. Clinical Testing
None

E. Sterilization
Device will be sterilized either by EtO (Ethylene Oxide) or Gamma radiation. EtO validation SAL: 10-6,and dosage less than 25ppm. Gamma radiation SAL: 10-6, and dosage 2.5mr to 4.5 mr.

F. Device Labeling
Labels is adequate.

3. Recommendation: The following deficiencies need to be addressed by the applicant in order for the review to continue:

1. Tier 1 certification is required. Please provide certification package with deficiency letter.

2. The label must bear the caution statement: CAUTION: Federal law restricts this device to sale by or on the order of a physician, as outlined in ODE Bluebook Memo G91-1, "Device Labeling Guidance", dated March 8, 1991. Copies of all guidance documents may be obtained from the Division of Small Manufacturers Assistance, CDRH, FDA, at 800-638-2041 or 301-443-6597.

Ronald A Rob

Date: 01/12/94
CFR Number: 884.4160
Product Code: HFG
Class: II

Date:
Concur / /
Do Not Concur / /
Comment:

The firm provided Tier-1 certification package and changed the labeling to include statement; "CAUTION: Federal law restricts this device to sale or on the order of a physician". Therefore, they have replied and met the deficiencies.

Gerry L. Pak 3/29/94.

RRG/LLD 1/6/93
Rev. 6/7/93

DRAERD Premarket Notification 510(k) Reviewer's Screening Checklist

510(k) Number &
Device Name K933094 Insufflation Tubing Kit w/Filter

Company Inman Medical Corporation

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

21

EPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

JULY 8, 1993

INMAN MEDICAL CORP.
ATTN: JOHN MAYALL
6316 AIRPORT FREEWAY
FORT WORTH, TX 76117

510(k) Number: K933094
Received: 06-24-93
Product: INSUFFLATOR TUBING KIT W/FILTER

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

ıe Safe Medical Devices Act of 1990 (SMDA), 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. Although the traditional timeframes for reviewing 510(k)s has been 90 days, it is now taking longer. These increasing response times have been caused by many factors, including a sharp increase in ODE's workload and increasingly complex device submissions. During 1992, we received about 1,500 more total submissions than we did the preceding year. We are troubled by these increases in response times and are making every effort to regain predictability in the timing of 510(k) reviews. Due to the increase in response times, CDRH has established a 510(k) Status Reporting System through which submitters may receive a status report on their 510(k) submissions(s) as follows:

- Beginning 90 days after ODE receives your 510(k) submission, you may begin requesting status information. Submit requests via fax (301-443-8818) or via mail to:
  510(k) Status Coordinator
  Division of Small Manufacturers Assistance (DSMA) (HFZ-220)
  Center for Devices and Radiological Health, FDA
  5600 Fishers Lane
  Rockville, Maryland 20857 USA
  Because of staff limitations, we cannot answer telephone status requests.

- 510(k) status requests should include:
  (1) submitter's name and mailing address;
  (2) requester's name, affiliation with the 510(k) submitter, mailing address, fax number (if applicable), telephone number, and signature; and

(3) 510(k) information, including product name, 510(k) number, date logged in by ODE (as identified in acknowledgment letter from ODE), and name of contact person identified on firm's 510(k) submission.

Enclosed is a suggested format that you may use to ensure that you include all of the required information.

- Within three working days after DSMA receives a submitter's status request, DSMA will send the submitter a fax or letter that includes:
  (1) the branch to which the 510(k) has been assigned;
  (2) the last action, and date of that action, that CDRH has taken regarding the 510(k), e.g., logging in an amendment, preparing a decision letter; and
  (3) the position of the 510(k) in the reviewer's queue.

We request that 510(k) submitters make status inquiries no more than every four weeks. We do not have the resources to respond more frequently.

The SMDA also requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new nd predicate device(s), or performance or clinical testing information. We nnot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages 510(k) submitters to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. **Since the law requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.**

Additionally, the new legislation also requires any person who asserts that their device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We nnot complete the review of your submission until you do so.

23

As of March 9, 1993, FDA has implemented the Good Manufacturing Practice (GMP) Pre-Clearance Inspection Program for all class III devices that are being reviewed under the premarket notification program. A letter of substantial equivalence cannot be sent until the finished device manufacturing site(s) and sterilization sites(s) as appropriate, have been identified and FDA has determined that the manufacturer(s) is in compliance with the GMP regulation (21 CFR Part 820).

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 227-8006.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

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 Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

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

24

IMC

K933094

June 17, 1992

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

RE: 510(k) Notification

Attention: Document Mail Clerk

In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR Part 807, premarket notification is hereby made of our intention to introduce into interstate commerce for commercial distribution the following device:

Classification Name: Product Code 85 HIF, Insufflator, Laparoscopic

Common/Usual Name: **Insufflator Tubing Kit w/Filter**

Proprietary Name: **Insufflator Tubing Kit w/Filter**

Establishment Registration Number: 1643958

Classification: We have been unable to locate the specific classification for this device, although we believe that the General and Plastic Surgery Panel would review this application.

Performance Standard: None established under Section 514.

Description: Description and materials of construction for this device are outlined in Exhibit #1A. Also outlined in Exhibit #1B are packaging and end product specifications.

Labeling: Copies of proposed labeling are attached as Exhibit #2.

Safety & Efficacy: We will provide safety and efficacy information to be made available upon request by any person.

Sterility: Sterility information is located in Exhibit #4.

Intended Use: This is a single use product supplied sterile. This device is intended for use during abdominal surgery.

INMAN MEDICAL CORP. • 6316 Airport Freeway • Fort Worth, Texas 76117 • 817-831-4700

Substantial Equivalence: This product is similar in design, composition and function to another product currently being marketed in the United States and abroad. A copy of the literature pertaining to this product can be found in Exhibit #3.

NOTE: All materials and components in this device are identical to the other products currently on the market as indicated in Exhibit #3.

We consider our intent to market this device as **confidential** commercial information and request that it be considered as such by FDA. We have not disclosed the intent to market this device to anyone except employees of our firm and have taken precautions to protect this confidentiality.

We would appreciate your reviewing the aforementioned information and attachments and returning your reply at your earliest convenience. If you have any additional questions, please call me, at: 800-553-8523.

Sincerely yours,

John Mayall
Director of Quality Assurance & Regulatory Affairs

DESCRIPTION OF MATERIALS OF CONSTRUCTION EXHIBIT #1A

PRODUCT: Insufflator Tubing Kit w/Filter

PRODUCT COMPONENTS DESCRIPTION:

1. MEDICAL GRADE PVC TUBING - Natvar Part# 607 (K850506)

2. FILTER - Pall Oxygenator Gas Line Filter, Model# ORO1. This filter has been marketed prior to 1976. (See letter from Pall)

3. LUER FITTINGS - Qosina Rotating Luer Fittings, Part# 990232 B/75, Polycarbonate. (K925147)

These components are substantially equivalent to the components in the device listed in Exhibit #3 which is currently in commercial use.

27

PACKAGING AND PACKAGING MATERIALS **EXHIBIT #1B**

PACKAGE,INDIVIDUAL; Product: Insufflator Tubing Kit w/Filter

Packackaging shall consist of a 3.0 mil, Tyvek laminated to 3.0 mil heat seal-coated Mylar. The package will be heat sealed and the packaging process will be validated. Production units will be sampled. Creep and burst force will be determined both prior to and after sterilization.

SHELF BOX:

The shelf box shall be constructed of Kraft paper.

SHIPPER CASE BOX:

The shipper case box shall be constructed of corrugated paper of 180 pound strength.

LABELING AND DIRECTIONS FOR USE EXHIBIT #2

PACKAGE LABEL

The following is the proposed text for the package label:

CONTAINS ONE (1) STERILE, INSUFFLATOR TUBING KIT w/FILTER: DO NOT USE IF PACKAGE HAS BEEN OPENED OR DAMAGED. THIS PACKAGE CONTAINS A SINGLE USE ONLY PRODUCT.

PRODUCT#: **LOT#:**

DIRECTIONS FOR USE:

1. **Remove the product from the peel pouch.**
2. **Insert luer connector into the insufflator luer or hose barb output port.**
3. **Connect the opposite luer connector to the verres needle or stopcock of the trocar sleeve.**
4. **Proceed with insufflation.**
5. **Properly dispose of this device upon completion of the procedure according to local regulations.**

CAUTION: RESTERILIZATION WILL COMPROMISE THE INTEGRITY OF THIS PRODUCT.

THIS DEVICE IS INTENDED FOR USE ONLY AS DESCRIBED AND IS CONTRAINDICATED WHERE ENDOSCOPIC SURGERY IS CONTRAINDICATED.

Inman Medical Corporation
6316 Airport Freeway
Haltom City, Texas 76117
817-831-4700

SHELF PACK BOX LABEL:
The proposed label for the shelf box shall be identical to the package label and will also contain the quantity.

SHIPPER CASE BOX LABEL:
The proposed label for the case box shall be identical to the shelf box label and will also contain the quantity.

31

SUBSTANTIAL EQUIVALENCE **EXHIBIT #3**

The following company manufactures a device substantially equivalent to the device we would like to market:

1. O.R. Concepts, Inc.
   200 N. Oak Street
   Roanoke, TX 76262
   800-826-3723
   K923818, K923908, K925147

2. Marlow Surgical Technologies, Inc.*
   1810 Joseph Lloyd Parkway
   Willoughby, OH 44094
   PRODUCT: OTT Insufflator Tubing/Filter, PROD#: 88-5050
   800-992-5581

3. Northgate Technologies*
   3930 Ventura Drive
   Arlington Heights, IL 60004
   PRODUCT: Northgate General Use Tubing Kit, PROD#: 7-510-12
   800-348-0424

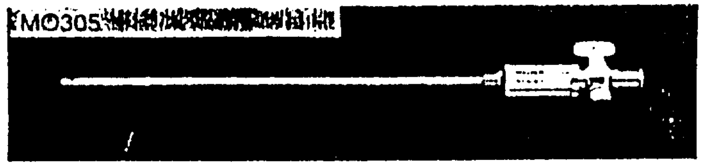
* I have enclosed a copy of their literature for your perusal.

32

EXHIBIT# 3
Page 2 of 3

I 'lators for Laparoscopic Procedures

MO305 [redacted]



Verres needle, 5", 12.7cm

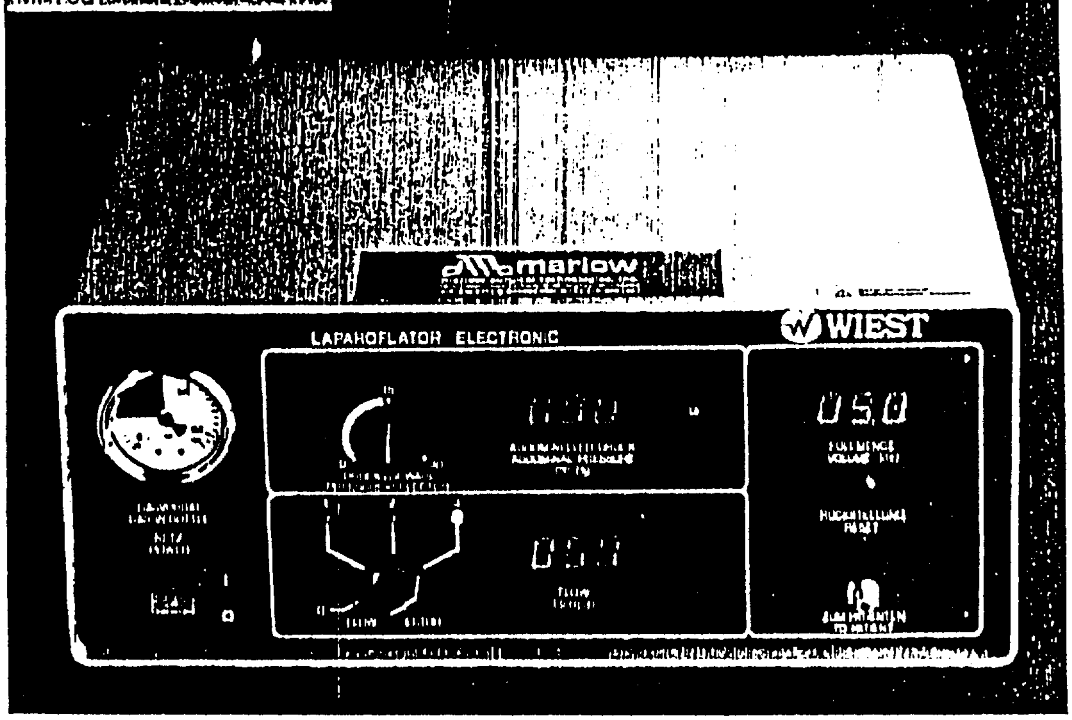
LMO304 [redacted]

Verres needle, 4", 10.3cm
(Not pictured.)

When it comes to insufflation, safety is paramount. Marlow Surgical Technologies creates instruments which administer pneumoperitoneum quickly, easily, and above all, safely. Single use and reusable instruments are tailored precisely for laparoscopic procedures—from Marlow, a company with fifteen years of experience specializing in laparoscopic instrumentation.

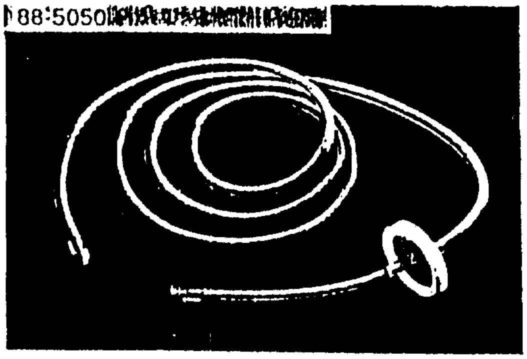
Because we listen to you, we are able to create the instruments I—like the Ott Insufflator Filter/Tubing™ which filters out debris from CO_2 tanks. It's just one innovation designed to make your job easier. Marlow Surgical. Where innovation begins with listening.

MR7051 [redacted]



Marlow-Wiest Electronic Laparoflator, high flow, 7 LPM. Lets operator set maximum intra-abdominal pressure (0-25mm hg) to ensure complete safety during pneumoperitoneum. Easy to read digital LED readouts. Once maximum pressure is set, operator "dials" in flow rates of 1 to 7 liters per minute. The microprocessor reads the intra-abdominal pressure and CO_2 gas flow is controlled automatically.

88-5050 [redacted]



REFERENCE: Douglas E. Ott, M.D., "Contamination via Gynecologic Endoscopy Insufflation," *Journal of Gynecologic Surgery*, Summer, 1989, 205-208.

Ott Insufflator Filter/Tubing™, sterile, single use. Prevents inorganic debris, rust and metal filings in standard CO_2 tanks [illegible] entering patients during [illegible]scopic procedures. [illegible]gned for today's high-flow insufflators, system will not adversely affect flow rates. Filter end attaches to either hose barb or luer lock style outlet on insufflator. Opposite end has luer connector for verres needle or primary trocar sleeve.

marlow
surgical technologies inc.
Where innovation begins with listening

1810 Joseph Lloyd Parkway
Willoughby, OH 44094
216/946-2453
[illegible]
Fax 216/946-[illegible]

OMNIFLATOR™ GENERAL USE KIT

CATALOG #7-510-12 **LOT #** 8BC001

INTENDED USE: To be used in conjunction with the NORTECH OMNIFLATOR™ 7400/7500 for insufflation.

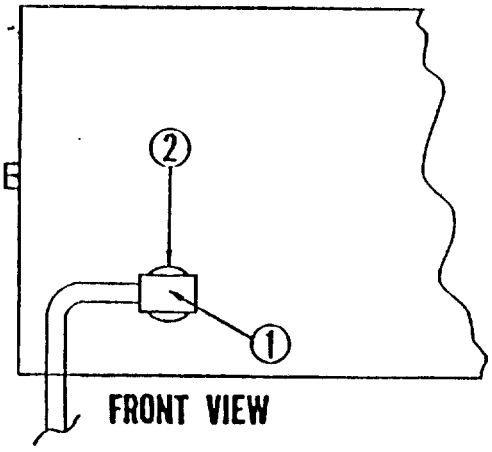
NOTE: STERILE (Unless package is damaged or opened).

INSTRUCTIONS FOR USE

This is a disposable sterile product designed for single patient use. Do not attempt to re-sterilize or re-use this product.

1. Tear off Tyvek™ cover to access sterile contents.
2. Place contents on sterile field.
3. Give the "Right Angle" (1) fitting to the circulating nurse for snap-in insertion into the "OMNIFLATOR"™ output port (2) located on the lower left hand corner of the front panel. The remaining tubing is kept in the sterile field.
4. Connect the luer-lock end of the tubing (in the sterile field) to the verres needle or stopcock of the trocar sleeve.
5. Proceed with insufflation.

NON-STERILE
SAMPLE
NOT FOR PATIENT USE



FRONT VIEW

NORTECH
NORTHGATE
TECHNOLOGIES
INCORPORATED

MANUFACTURED FOR
NORTHGATE TECHNOLOGIES INC.
3930 Ventura Dr., Suite 150
Arlington Hts., IL 60004
(800) 348-0424

53-10201-3 4/91

STERILIZATION **EXHIBIT #4**

METHOD:

This device will be sterilized by either EtO (Ethylene Oxide) or Gamma Radiation.

VALIDATION:

EtO: The validation of the sterilization cycle shall be by the "half-cycle", AAMI method and shall be performed on no less than three (3) product lots.

SAL: 10-6 (Ten to the minus six)

If EtO sterilization is used we agree to meet the standards set forth by the FDA in the Federal Register, Vol.43, No.122 - Friday, June 23, 1978, (#27482) regarding EtO Residue Levels. We will not exceed twenty-five (25) parts per million in the manufacture of this device.

Sterility Test Procedure and Verification are as per USP XXII.

Our EtO Sterilizer is: Lemco Enterprises, Inc.,621 1/2 Interstate Drive, Ardmore, OK 73402. Phone #: 405-226-7808.

GAMMA: The validation of the sterilization process shall be by the AAMI B.1 Method.

SAL: 10-6 (Ten to the minus six)

DOSAGE: 2.5mr to 4.5mr

Our Gamma Sterilizer is: SteriGenics Inc., 3001 Wichita Court, Ft. Worth, Texas 76140. Phone #: 817-293-0999.

35