Records processed under FOIA Request #2016-2105

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(cwf)
FOLDER:	K946147 - 118 pages
COMPANY:	KARL STORZ ENDOSCOPY-AMERICA, INC. (KARLSTORENDOAMER)
PRODUCT:	LAPAROSCOPE, GYNECOLOGIC (AND ACCESSORIES) (HET)
SUMMARY:	Product: KSE STEINER ELECTROMECHANIC MORCELLATOR
DATE REQUESTED:	Aug 30, 2016
DATE PRINTED:	Aug 30, 2016
Note:	Printed

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

Records processed under FOIA Request #2015-0[illegible]

Storz
scopy, A[illegible]
[illegible] Corporate Pointe
[illegible] California 90230-6600
Phone [illegible] 568-1500

STORZ
Karl Storz Endoscopy

SUMMARY OF SAFETY AND EFFECTIVENESS

MAY 25 1995

The Karl Storz Steiner Electromechanic Morcellator and accessories and the predicate devices are motorized surgical devices which morcellate and remove tissue from the surgical site. These instruments are designed for use by qualified surgeons during gynecological endoscopic procedures.

The device comes into contact with the human body for brief periods of time. The body contact material is commonly used in medical devices for a wide range of applications, and has a long history of biocompatibility for human use.

The Karl Storz Steiner Electromechanic Morcellator and accessories is substantially equivalent to the predicate devices since the basic features, design, and intended uses are the same. The minor differences in design and dimensions between the Karl Storz Steiner Electromechanic Morcellator and accessories and the predicate devices raise no new issues of safety and effectiveness as these design differences have no effect on the performance, function, or intended use of the devices.

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

Records processed under FOIA Request #2016-2105

K946147/A3

RECIEVED

17 MAY 95 10 30

FDA/CDRH/CDE/DMC

Karl Storz
Endoscopy-America, Inc.

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

Toll Free 800 421 0837
Fax 310 410 [illegible]

Ref to :
95-046- MA

May 16, 1995

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

Re: K946147 (Karl Storz Steiner Electromechanic Morcellator and Accessories for use in Gynecology)

Dear Sir or Madam:

Additional information as requested by phone from Donna-Bea Tillman on May 16, 1995 is provided below.

1. Please provide either certification that your device complies with an applicable standard for electromagnetic compatibility specifically IEC 601-1-2, or provide test data demonstrating an equivalent level of protection.

KSEA certifies that the Steiner Electromechanic Morcellator complies with IEC-601-1-2.

We hope that the enclosed information will enable FDA to clear this application without any further delay. If there are additional questions, please contact me at the following number: 1-800-421-0837, ext. 331.

Sincerely,

Marika Anderson

Marika Anderson
Regulatory Affairs Specialist

cc: T. Richards
K946147
Chron

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

Records processed under FOIA Request #2016-2105

K946147 / A5

KARL STORZ "Add to File" K946147
Steiner Electromechanical Morcellator
Cover Letter *(including E-Copy Statement)*

May 20, 2016

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (WO66-G609)
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA/CDRH/DCC
MAY 23 2016
RECEIVED

Subject: "Add to File" Supplement to 510(k) Premarket Notification for KSEA Steiner Electromechanical Morcellators cleared under K946147.

Attn: Division of Reproductive, Gastro-Renal, and Urological Devices (DRGUD)
Obstetrics and Gynecology Devices Branch (OGDB)

Dear Sir or Madam,

An electronic copy has been included as part of this submission. The eCopy is an exact duplicate of the paper copy.

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FDC Act), Karl Storz Endoscopy-America, Inc. hereby submits this "Add to File" supplement to 510(k) Notification K946147 for the Steiner Electromechanical Morcellators.

Common Name: Laparoscopic Powered Morcellator
Proprietary Name: KSEA Steiner Electromechanical Morcellators
510(k) Number: K946147
Regulation Number: 21 CFR 884.1720
Product Code: HET
Device Class: Class II
Review Panel: Obstetrics/Gynecology

The Submitter of this 510(k) is KARL STORZ Endoscopy America Inc. (KSEA), located at 2151 E. Grand Avenue, El Segundo, CA 90245.

The manufacturer of the Steiner Electromechanical Morcellator is KARL STORZ GMBH & CO. KG (Establishment Registration number: 9610617), located at Mittelstrasse 8, Tuttlingen Baden-Wurttemberg, Germany 78532.

The initial importer/distributor of the device is KARL STORZ Endoscopy America, Inc. Southbridge (KSEA, Establishment Registration number: 2020550), located at 15 Wells Street Southbridge, MA 01550.

On November 25, 2014, the FDA issued the Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators. In the guidance document, the FDA recommended that manufacturers of Laparoscopic Power Morcellators with a general indication or a specific gynecologic

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

92

indication prominently include the following Contraindications and Boxed Warning in their product labeling:

> *CONTRAINDICATION: Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.*
>
> *CONTRAINDICATION: Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are:*
>
> - *peri- or post-menopausal, or*
> - *candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy* incision.

WARNING: **Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.**

KARL STORZ has determined that the Steiner Electromechanical Morcellator originally cleared under 510(k) K946147 with indications for use during general surgery endoscopic procedures, and gynecological endoscopic surgical procedures, including removal/morcellation of myomata falls within the scope of this guidance document.

At this time, KARL STORZ is no longer distributing the Steiner Electromechanical Morcellator in the United States. If at a future date KARL STORZ decides to reintroduce the product, an add-to-file with updated labeling will be submitted.

If there are any questions regarding this submission, please contact:

Contact Information: Leigh Spotten
Director, Regulatory Affairs
Karl Storz Endoscopy-America, Inc.
2151 E. Grand Avenue
El Segundo, CA 90245-5017
Tel.: (424) 218-8738
Fax: (424) 218-8519
Email: Leigh.Spotten@karlstorz.com

Sincerely,

Leigh Spotten
Director, Regulatory Affairs

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

Records processed under FOIA Request #2016-2105

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
May 20, 2016	N/A - Add to Existing File	K946147

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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: KARL STORZ Endoscopy - America, Inc.	Establishment Registration Number *(if known)*: 3010202439		
Division Name *(if applicable)*:	Phone Number *(including area code)*: 424-218-8738		
Street Address: 2151 E. Grand Ave.	FAX Number *(including area code)*: 424-214-8519		
City: El Segundo	State / Province: CA	ZIP/Postal Code: 90254	Country: USA
Contact Name: Leigh Spotten			
Contact Title: Director, Regulatory Affairs	Contact E-mail Address: Leigh.Spotten@karlstorz.com		

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

Company / Institution Name:			
Division Name *(if applicable)*:	Phone Number *(including area code)*:		
Street Address:	FAX Number *(including area code)*:		
City:	State / Province:	ZIP Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

PSC Publishing Services (301) 443-6740 EF

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

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] New Device
- [ ] 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

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

- [ ] Response to FDA correspondence:

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

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

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

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

- [ ] 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

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

- [ ] Response 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

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [x] Other Reason *(specify)*:

Add to File supplement to K946147, in response to Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators

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

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	N/A	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- ☐ 510 (k) summary attached
- ☐ 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	N/A (Add to File) K946147	1		1	
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Laparoscopic Powered Morcellator

	Trade or Proprietary or Model Name for This Device		Model Number
1	Steiner Electromechanical Morcellator	1	
2		2	
3		3	
4		4	
5		5	

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

1 K946147	2	3	4	5	6
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: HET

C.F.R. Section *(if applicable)*: 884.1720

Classification Panel: Gastroenterology/Urology

Device Class

☐ Class I ☒ Class II

☐ Class III ☐ Unclassified

Indications *(from labeling)*

KSEA Steiner Electromechanic Morcellator is intended to be used during gynecological endoscopic surgical procedures, including removal/morcellation of myomata and uteri at hysterectomy.

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

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)* K946147

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name KARL STORZ GMBH & CO. KG		Establishment Registration Number 9610617		
Division Name *(if applicable)*		Phone Number *(including area code)* (424) 218-8201		
Street Address Mittelstrasse 8		FAX Number *(including area code)* (424) 218-8519		
City Tuttlingen		State / Province Baden-Wurttemberg	ZIP Code 78532	Country Germany
Contact Name SUSIE S. CHEN	Contact Title Director, International Regulatory Affairs		Contact E-mail Address Su.Chen@karlstorz.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) 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 Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) 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 Code	Country
Contact Name	Contact Title		Contact E-mail Address	

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

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.

1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

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

Records processed under FOIA Request #2016-2105

May 20, 2016

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (WO66-G609)
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Subject: "Add to File" Supplement to 510(k) Premarket Notification for KSEA Steiner Electromechanical Morcellators cleared under K946147.

Attn: Division of Reproductive, Gastro-Renal, and Urological Devices (DRGUD)
Obstetrics and Gynecology Devices Branch (OGDB)

Dear Sir or Madam,

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Common Name: Laparoscopic Powered Morcellator
Proprietary Name: KSEA Steiner Electromechanical Morcellators
510(k) Number: K946147
Regulation Number: 21 CFR 884.1720
Product Code: HET
Device Class: Class II
Review Panel: Obstetrics/Gynecology

The Submitter of this 510(k) is KARL STORZ Endoscopy America Inc. (KSEA), located at 2151 E. Grand Avenue, El Segundo, CA 90245.

The manufacturer of the Steiner Electromechanical Morcellator is KARL STORZ GMBH & CO. KG (Establishment Registration number: 9610617), located at Mittelstrasse 8, Tuttlingen Baden-Wurttemberg, Germany 78532.

The initial importer/distributor of the device is KARL STORZ Endoscopy America, Inc. Southbridge (KSEA, Establishment Registration number: 2020550), located at 15 Wells Street Southbridge, MA 01550.

On November 25, 2014, the FDA issued the Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators. In the guidance document, the FDA recommended that manufacturers of Laparoscopic Power Morcellators with a general indication or a specific gynecologic

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

indication prominently include the following Contraindications and Boxed Warning in their product labeling:

> *CONTRAINDICATION: Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.*
>
> *CONTRAINDICATION: Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are:*
>
> - *peri- or post-menopausal, or*
> - *candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy* incision.

***WARNING:* Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.**

KARL STORZ has determined that the Steiner Electromechanical Morcellator originally cleared under 510(k) K946147 with indications for use during general surgery endoscopic procedures, and gynecological endoscopic surgical procedures, including removal/morcellation of myomata falls within the scope of this guidance document.

At this time, KARL STORZ is no longer distributing the Steiner Electromechanical Morcellator in the United States. If at a future date KARL STORZ decides to reintroduce the product, an add-to-file with updated labeling will be submitted.

If there are any questions regarding this submission, please contact:

Contact Information: Leigh Spotten
Director, Regulatory Affairs
Karl Storz Endoscopy-America, Inc.
2151 E. Grand Avenue
El Segundo, CA 90245-5017
Tel.: (424) 218-8738
Fax: (424) 218-8519
Email: Leigh.Spotten@karlstorz.com

Sincerely,

Leigh Spotten
Director, Regulatory Affairs

Redacted per FOIA Request #2016-2105

MAY 25 1995

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Marika Anderson
Regulatory Affairs Specialist
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe
Culver City, California 90230-7600

Re: K946147/A
Steiner Electromechanic Morcellator:
GYN Laparoscopic Applications
Dated: March 21, 1995
Received: March 22, 1995
Regulatory Class: II
21 CFR 884.1720/Procode: 85 HET

Dear Ms. Anderson:

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 or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug and Cosmetic Act (Act). You may therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you may have under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of 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 for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) 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

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

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

Records processed under FOIA Request #2016-2105

510(K) ROUTE SLIP

510(k) NUMBER K946147 PANEL OB DIVISION DRAER BRANCH OGDB

TRADE NAME KSE STEINER ELECTROMECHANIC MORCELLATOR

COMMON NAME TISSUE MORCELLATOR

PRODUCT CODE ___

APPLICANT KARL STORZ ENDOSCOPY-AMERICA, INC.
SHORT NAME KARLSTORENDOAMER
CONTACT MARIKA ANDERSON
DIVISION
ADDRESS 600 COROPORATE POINTE
CULVER CITY, CA 902307600
PHONE NO. (310) 558-1500 FAX NO. (310) 410-5527

MANUFACTURER KARL STORZ ENDOSCOPY-AMERICA, REGISTRATION NO. 2020550

DATE ON SUBMISSION 14-DEC-94 DATE DUE TO 510(K) STAFF 01-MAR-95

DATE RECEIVED IN ODE 16-DEC-94 DATE DECISION DUE 16-MAR-95

DECISION __ DECISION DATE _____

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	21-MAR-95	22-MAR-95	05-JUN-95	20-JUN-95	

CORRESPONDENCE	SENT	DUE BACK	
C001	27-FEB-95	29-MAR-95	HOLD LETTER

OTHER SUBMISSIONS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
ADD-TO-FILE	26-JAN-95	27-JAN-95			
ADD-TO-FILE	10-FEB-95	13-FEB-95			

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

Records processed under FOIA Request #2016-2105

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date March 24, 1995

From REVIEWER(S) - NAME(S) Donna-Bea Tillman

Subject 510(k) NUMBER K946147/S1

To THE RECORD -- It is my recommendation that the subject 510(k) Notification:

- [x] Is substantially equivalent to marketed devices.
- [ ] Requires premarket approval. NOT substantially equivalent to marketed devices.
- [ ] Requires more data.
- [ ] Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance? [ ] YES [x] NO

Is this device subject to the Tracking Regulation? [ ] YES [x] NO

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

This 510(k) contains: Truthful and Accurate Statement ~~[ ] Requested [ ] Enclosed~~ NA
(required for originals received 3-14-95 and after)

- [x] A 510(k) summary OR [ ] A 510(k) statement
- [ ] 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 with panel and class:
85 HET Class II
884.1720

Additional Product Code(s) with panel (optional):

REVIEW: Colin M. Pollard (BRANCH CHIEF) OGDB (BRANCH CODE) 3/24/95 (DATE)

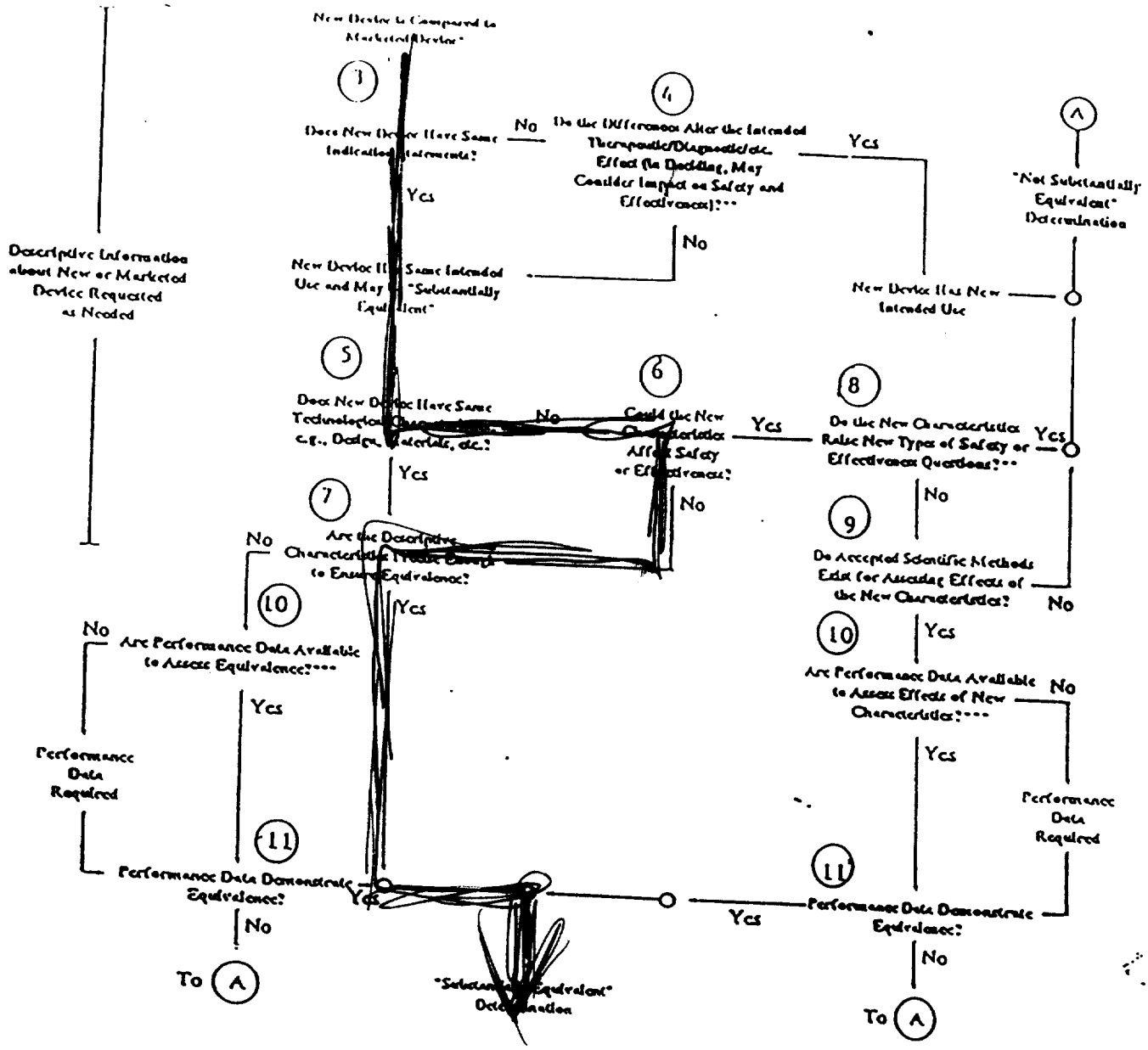
FINAL REVIEW: D. Pilton for LYin (DIVISION DIRECTOR) 5/24/95 (DATE)

Revised 3/8/95

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

Records processed under FOIA Request #2016-2105

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.

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

Records processed under FOIA Request #2016-2105

OGDB

K946147/A

Reviewer: *Donna-Bea Tillman*
Biomedical Engineer

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

Proprietary Trade Name: Steiner Electromechanic Morcellator
Common Name: Morcellator, Laparoscope, Accessory

Product to which compared: Cook morcellator (K925851)

Applicant: Karl Storz Endoscopy
600 Corporate Pointe
Culver City, CA 90230

Contact: Marika Anderson
Regulatory Affairs Specialist
Phone: (310) 558-1500,x331

Intended Use:

The Steiner Electromechanic Morcellator is intended to be used for the morcellation and removal of soft tissue during gynecologic endoscopic procedures. Indications for the removal of uteri at hysterectomy were removed in the February 10, 1995, FAX from Karl Storz.

	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?	_	X
• Is the device for prescription?	X	_
• Does the device contain a drug or biological product as a component?	_	X
• Is this device a kit?	_	X

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

Records processed under FOIA Request #2016-2105

Provide a brief overview of the device, its design, principle of operation, and functional/performance characteristics.

The Karl Storz Steiner Electromechanic Morcellator is a reusable, motor-driven system intended for the laparoscopic morcellation and removal of soft tissue. The system comprises the Morcellator handle, motor, cutters, trocars, claw forceps, connecting cord, footswitch, and control unit. The morcellator consists of a 12 mm diameter, 20 cm long cannula connected to a handle that houses the motor. The cutter is a 11 mm diameter sharpened tube that fits inside the cannula. The cutter oscillates at speeds up to 300 rpm, and cutting directions can be controlled by a two-pedal footswitch. The trocars are 10 mm in diameter and 29.5 cm in length, and they are available with either conical or pyramidal tips. The claw forceps are 10 mm in diameter and 36 cm in length. All body contacting components are made of surgical grade stainless steel.

To use the device, the trocar is inserted into the lumen of the cutter, and the abdominal wall is punctured. The trocar is then removed and replaced with the claw forceps. The surgeon uses the claw forceps to grasp the tissue to be removed and to pull it to the edge of the cutter. The cutter excises a cylindrical piece of tissue, which is removed from the lumen of the cutter using the claw forceps.

REVIEW ANALYSIS

This 510(k) was received on December 14, 1994. In late January 1995 I was contacted by Dan Shultz, M.D., of the General Surgery Branch who informed me that he had just found the device to be substantially equivalent for general surgery uses. He discussed with me several of the labeling changes that he had requested. I requested a clinical consult from OGDB medical officer Eugene Williams, M.D., and Dr. Williams reported that except for one minor correction, the labeling changes requested by Dr. Shultz had addressed all of his concerns. However, following a discussion with OGDB Branch Chief Colin Pollard, it was decided that Karl Storz should be asked to provide more specific indications for use. There were also several minor technical issues that remained to be addressed. Karl Storz was sent a request for additional information dated February 27, 1995, and they replied with a response dated March 21, 1995.

Response to Deficiencies

1. *Please provide either certification that your device complies with an applicable standard for electromagnetic compatibility (e.g., IEC 601-1-2), or provide test data demonstrating an equivalent level of protection.*

   On May 16, 1995, I received a FAX from Karl Storz certifying that the device complies with IEC 601-1-2. This deficiency is satisfied.

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

Records processed under FOIA Request #2016-2105

2. *Because the morcellator handle will be held by the surgeon, it should be sterilized, not merely disinfected. Please modify your instruction manual to remove all references to disinfection as an appropriate endpoint for reprocessing of the morcellator handle.*

   The labeling was modified as requested. This deficiency is satisfied.

3. *Please describe the methods used to validate each of your recommended sterilization procedures.*

   The AAMI overkill method to a SAL of 10^{-6} will be used. This deficiency is satisfied.

4. *Please modify your labeling to include indications for use (e.g., removal of myomata).*

   The indications for use were modified to include removal of myomata. I discussed the labeling of this device with OGDB panel member Barbara Levy, M.D., on May 15, 1995, and she felt that the indications and warnings provided by Karl Storz were adequate.

5. *As discussed during our February 22, 1995, tele-conference, please modify your caution statement against use of the device for dissection to include specific examples.*

   Karl Storz added the following statement to their labeling: "Ovaries, fallopian tubes, myomata and other structures must be devascularized and dissected before morcellation". As noted above, Dr. Levy felt that this revised labeling is adequate.

Provide an overview of the review principles and findings that were used to support the reviewer recommendation.

The Karl Storz Electromechanic Morcellator is a reusable, motor-driven system intended for the laparoscopic morcellation and removal of soft tissue. Karl Storz has claimed substantial equivalence to the Cook tissue morcellator. The Cook device uses a vacuum to pull the tissue against the morcellator, while the Karl Storz device uses grasping forceps. This new technological characteristic does not raise any new questions of safety and effectiveness, and the descriptive characteristics are precise enough to ensure that the Karl Storz device is equivalent to the Cook device. The labeling is complete and consistent with the intended use of the device. Therefore, I recommend that the karl Storz Steiner Electromechanic Morcellator be found Substantially Equivalent to predicate electromechanic morcellators.

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

Records processed under FOIA Request #2016-2105

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, GOTO 5
4.	Do differences alter the effect er raise new issues of safety or effectiveness?	_	_	IF YES,STOP->NSE
5.	Same technological characteristics?	_	X	IF YES, GOTO 7
6.	Could the new characteristics Affect safety or effectiveness?	_	X	IF YES, GOTO 8
7.	**Descriptive characteristics precise enough?**	X	_	**IF YES, STOP->SE**

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

Records processed under FOIA Request #2016-2105

REVIEWER RECOMMENDATION

Substantially Equivalent

ProCode: 85 HET
Class: II
CFR #: 21 CFR §884.1720

Donna-Bea Tillman 5/16/95
Donna-Bea Tillman, Ph.D Date

Colin M. Pollard 5/22/95
Colin M. Pollard
Chief, Ob/Gyn Devices Branch Date

/✓/ Concur
/ / Do not concur.
Comments:

9

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

Karl Storz
Endoscopy-America, Inc.

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

Toll Free 800 421 0837
Fax 310 410 5527.

DATE: 5/16/94

TO: Donna-Bea Tillman FAX: (301) 480-4224

FROM: Marika Anderson FAX: (310) 410-5519

OFFICE TEL: (310) 558-1500X331

NUMBER OF PAGES INCLUDING THIS COVER SHEET: 2

RE: K946147

MESSAGE: Here's the information you requested. Hard copy will follow.

Marika Anderson

PRIVACY NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone and return the original message to us at the above address via regular U.S. mail.

10

Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe
Culver City, California 90230-7600
Phone 310 558 1500
Toll Free 800 421 0837
Fax 310 410 5527

Ref to :
95-046- MA

May 16, 1995

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

Re: K946147 (Karl Storz Steiner Electromechanic Morcellator and Accessories for use in Gynecology)

Dear Sir or Madam:

Additional information as requested by phone from Donna-Bea Tillman on May 16, 1995 is provided below.

1. Please provide either certification that your device complies with an applicable standard for electromagnetic compatibility specifically IEC 601-1-2, or provide test data demonstrating an equivalent level of protection.

KSEA certifies that the Steiner Electromechanic Morcellator complies with IEC-601-1-2.

We hope that the enclosed information will enable FDA to clear this application without any further delay. If there are additional questions, please contact me at the following number: 1-800-421-0837, ext. 331.

Sincerely,

Marika Anderson

Marika Anderson
Regulatory Affairs Specialist

cc: T. Richards
K946147
Chron

Records processed under FOIA Request #2016-2105

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

March 24, 1995

KARL STORZ ENDOSCOPY-AMERICA, INC.
600 COROPORATE POINTE
CULVER CITY, CA 90230
ATTN: MARIKA ANDERSON

510(k) Number: K946147
Product: KSE STEINER ELECTROMECHANIC MORCELLATOR

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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

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

Sincerely yours,

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

10

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

Records processed under FOIA Request #2016-2105

K946147

Karl Storz
Endoscopy-America, Inc.

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

Toll Free 800 421 0837
Fax 310 410 5527

Ref to :
95-029- MA

March 21, 1995

RECEIVED
22 MAR 95 12 32
FDA/CDRH/ODE/DMC

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

Re: K946147 (Karl Storz Steiner Electromechanic Morcellator and Accessories for use in Gynecology)

Dear Sir or Madam:

Additional information as requested by letter dated February 27, 1995 is provided below.

1. Please provide either certification that your device complies with an applicable standard for electromagnetic compatibility (e.g., IEC 601-1-2), or provide test data demonstrating an equivalent level of protection.

KSEA certifies that the Steiner Electromehanic Morcellator complies with IEC-601-1.

2. Because the Morcellator handle will be held by the surgeon, it should be sterilized, not merely disinfected. Please modify your instruction manual to remove all references to disinfection as an appropriate endpoint for reprocessing of the morcellator handle.

Reference to disinfection has been removed from the instruction manual. See attachment 1 for revised instruction manual pages.

3. Please describe the methods used to validate each of your recommended sterilization procedures.

AAMI overkill method with an SAL of 10^{-6}.

13

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

4. Please modify the indication for use statement in your labeling to include specific examples (e.g., removal of myomata).

Please see attachment 2 for the labeling indication for use statement.

5. As discussed during our February 22, 1995 tele-conference, please modify your caution statement against use of the device for dissection to include specific examples.

Please see attachment 2 for the modified caution statement.

We hope that the enclosed information will enable FDA to clear this application without any further delay. If there are additional questions, please contact me at the following number: 1-800-421-0837, ext. 331

Sincerely,

Marika Anderson

Marika Anderson
Regulatory Affairs Specialist

cc: T. Richards
K946147
Chron

14

ATTACHMENT 1

Records processed under FOIA Request #2016-2105

DRAFT

Changing the cutting knife

Caution: Always pull out the power plug beforehand!

1. Unscrew the black screw cap at the proximal end of the handle.

2. Remove the larger screw cap at the distal end of the handle. The cutting knife can now be pulled out.

3. Insert the new cutting knife. Then reassemble the handle in reverse sequence.

Fuse replacement

Caution: Always pull out the power plug beforehand!

1. Remove the power fuse holder with a screwdriver or other tool.

2. Insert new fuses of the appropriate rating.

3. Replace power fuse holder.

Cleaning and care of the unit

Caution: Always pull out power plug before cleaning.

The instrument surface should be cleaned with a mild cleaning agent or disinfectant. Do not allow any cleaning liquid to get into the instrument.
The morcellator handle and the motor may be steam or gas sterilized

The connecting cord may be steam or gas sterilized.
Do not disinfect the connecting cord in antiseptic solutions.

Manufacturer's warranty

For **one** year as of delivery to the end customer we agree to replace the goods free of charge if proof can be provided of faulty materials or faulty workmanship. In doing so we cannot accept to bear the cost of transportation or the risk of shipment. The warranty referred to in § 3 of our Standard conditions of Business shall apply.

Opening the equipment or performance of any repairs or modifications of the equipment by unauthorized persons shall relieve us of any liability for its performance. Any such opening, repair or modification during the warranty period shall void all warranty.

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

Records processed under FOIA Request #2016-2105

DRAFT

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1. Remove the power fuse holder with a screwdriver or other tool.
2. Insert new fuses of the appropriate rating.
3. Replace power fuse holder.

Cleaning and care of the unit

Caution: Always pull out power plug before cleaning.

The instrument surface should be cleaned with a mild cleaning agent or disinfectant. Do not allow any cleaning liquid to get into the instrument.

The morcellator handle and the motor may be steam or gas sterilized or disinfected in cold antiseptic solutions.

The connecting cord may be steam or gas sterilized.

Do not disinfect the connecting cord in antiseptic solutions.

Manufacturer's warranty

For **one** year as of delivery to the end customer we agree to replace the goods free of charge if proof can be provided of faulty materials or faulty workmanship. In doing so we cannot accept to bear the cost of transportation or the risk of shipment. The warranty referred to in § 3 of our Standard conditions of Business shall apply.

Opening the equipment or performance of any repairs or modifications of the equipment by unauthorized persons shall relieve us of any liability for its performance. Any such opening, repair or modification during the warranty period shall void all warranty.

ATTACHMENT 2

Records processed under FOIA Request #2016-2105

DRAFT

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

CAUTION: The use of a tissue extraction bag is recommended for the morcellation of malignant tissue or tissue suspected of being malignant and for tissue that the surgeon may consider to be harmful when disseminated in a body cavity.

CAUTION: This device is specifically contraindicated for use on vascularized tissue and as a dissecting tool. Ovaries, fallopian tubes, myomata and other structures must be devascularized and dissected before morcellation.

INTENDED USE: This device is intended for use during gynecological endoscopic procedures, including removal/morcellation of myomata.

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

Records processed under FOIA Request #2016-2105

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30

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

Records processed under FOIA Request #2016-2105

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Marika Anderson
Regulatory Affairs Specialist
Karl Storz Endoscopy
600 Corporate Pointe
Culver City, California 90230

FEB 27 1995

Re: K946147
Steiner Electromechanic Morcellator
Dated: December 14, 1994
Received: December 16, 1994

Dear Ms. Anderson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following additional information:

1. Please provide either certification that your device complies with an applicable standard for electromagnetic compatibility (e.g., IEC 601-1-2), or provide test data demonstrating an equivalent level of protection.

2. Because the morcellator handle will be held by the surgeon, it should be sterilized, not merely disinfected. Please modify your instruction manual to remove all references to disinfection as an appropriate endpoint for reprocessing of the morcellator handle.

3. Please describe the methods used to validate each of your recommended sterilization procedures.

4. Please modify the indication for use statement in your labeling to include specific examples (e.g., removal of myomata).

5. As discussed during our February 22, 1995, tele-conference, please modify your caution statement against use of the device for dissection to include specific examples.

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

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(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

21

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

Records processed under FOIA Request #2016-2105

Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

The requested information should reference your above 510(k) number and should be submitted in duplicate to:

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

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

If you have any questions concerning the contents of this letter, please contact Donna-Bea Tillman, Ph.D., at (301) 594-1180. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Colin M. Pollard

Colin M. Pollard
Chief, Obstetrics/Gynecology Devices Branch
Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Records processed under FOIA Request #2016-2105

Ms. Marika Anderson
Regulatory Affairs Specialist
Karl Storz Endoscopy
600 Corporate Pointe
Culver City, California 90230

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Sincerely yours,

/S/

Colin M. Pollard
Chief, Obstetrics/Gynecology Devices Branch
Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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

DBTillman
C:\WP51\FILES\K946147
Draft:2/21/95:ens

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Z-470	DTillman	2/23/95						
Z470	Pollard	2/24/95						

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

Records processed under FOIA Request #2016-2105

Memorandum

Date February 23, 1995

From REVIEWER(S) - NAME(S) Donna-Bea Tillman

Subject 510(k) NOTIFICATION K946147

To THE RECORD

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

_____ (A) Is substantially equivalent to marketed devices.

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

__X__ (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:

_____

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

_____

REVIEW: Colin M Pollard (BRANCH CHIEF) | OGDB (BRANCH CODE) | 2/24/95 (DATE) (FMP)

FINAL REVIEW: _____ (DIVISION DIRECTOR) (DATE)

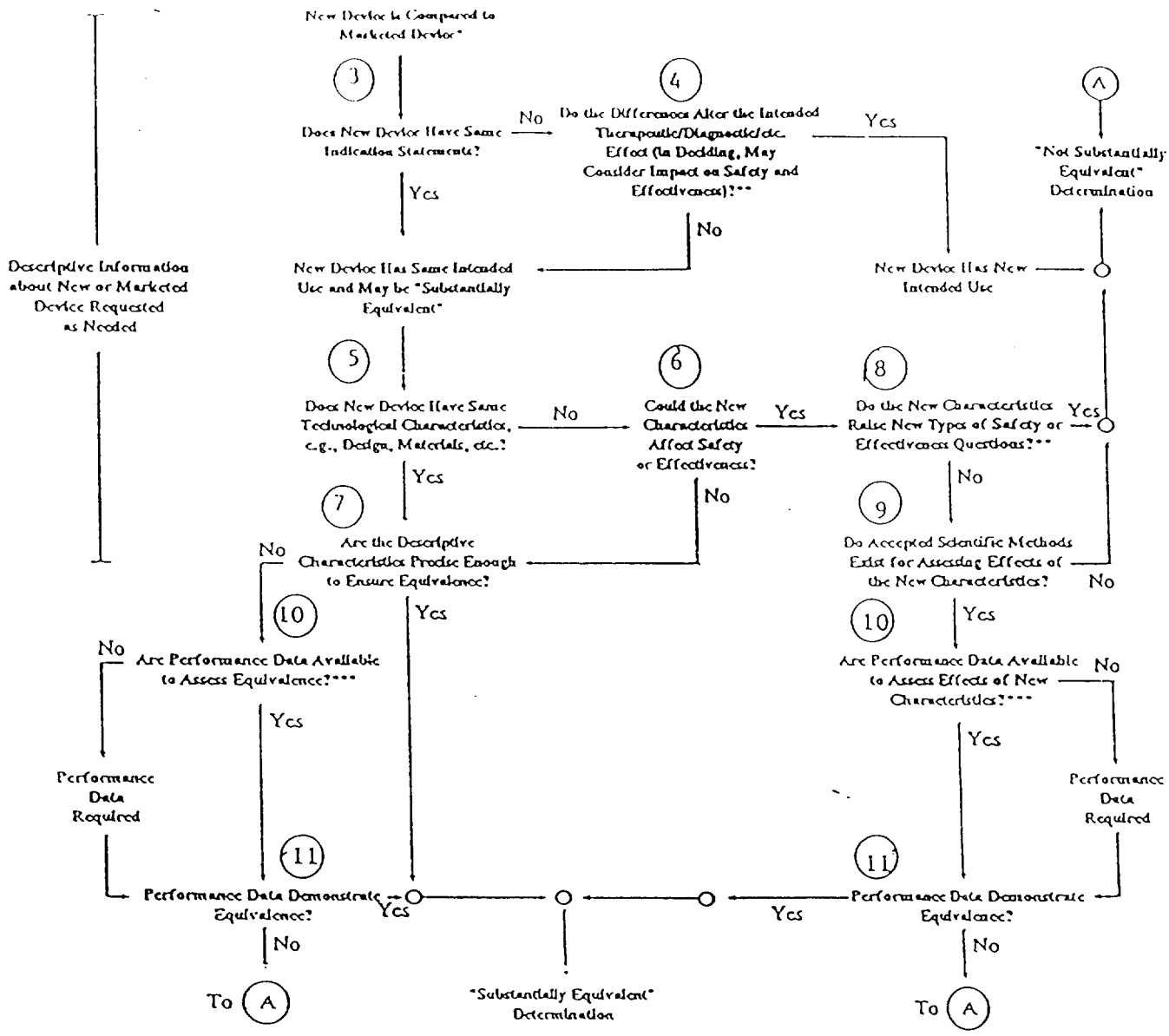
*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

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

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

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.

Records processed under FOIA Request #2016-2105

Records processed under FOIA Request #2016-2105

OGDB

K946147

Reviewer: *Donna-Bea Tillman*
Biomedical Engineer

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

Proprietary Trade Name: Steiner Electromechanic Morcellator
Common Name: Morcellator, Laparoscope, Accessory

Product to which compared: Cook morcellator (K925851)

Applicant: Karl Storz Endoscopy
600 Corporate Pointe
Culver City, CA 90230

Contact: Marika Anderson
Regulatory Affairs Specialist
Phone: (310) 558-1500,x331

DEVICE DESCRIPTION

1. *Intended Use:*

The Steiner Electromechanic Morcellator is intended to be used for the morcellation and removal of soft tissue during gynecologic endoscopic procedures. Indications for the removal of uteri at hysterectomy were removed in the February 10, 1995, FAX from Karl Storz.

2. *Physical Description:*

	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?	_	X
• Is the device for prescription?	X	_
• Does the device contain a drug or biological product as a component?	_	X
• Is this device a kit?	_	X

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

Records processed under FOIA Request #2016-2105

Provide a brief overview of the device, its design, principle of operation, and functional/performance characteristics.

The Karl Storz Steiner Electromechanic Morcellator is a reusable, motor-driven system intended for the morcellation and removal of soft tissue. The system comprises the Morcellator handle,

(b)(4)

[redacted]

To use the device, the trocar is inserted into the lumen of the cutter, and the abdominal wall is punctured. The trocar is then removed and replaced with the claw forceps. The surgeon uses the claw forceps to grasp the tissue to be removed and to pull it to the edge of the cutter. The cutter excises a cylindrical piece of tissue, which is removed from the lumen of the cutter using the claw forceps.

This device was found Substantially Equivalent for general surgical use by the General Surgery Branch on January 27, 1995.

REVIEW ANALYSIS

- *Component Materials*

  All patient contacting components are made of AISI series 303 or 304 surgical grade stainless steel, with the exception of the forceps jaws, which are series 420.

- *Performance Characteristics/Features of Device*

  This AC-powered device complies with UL 544 for electrical safety. The firm did not address the issue of electromagnetic compatibility.

  x. Please provide either certification that your device complies with an applicable standard for electromagnetic compatibility (e.g., IEC 601-1-2), or provide test data demonstrating an equivalent level of protection.

- *Sterilization*

  The Steiner Electromechanic Morcellator is a reusable medical device. The morcellator handle and the motor may be steam or gas sterilized, or disinfected in a liquid disinfectant.

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

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Because the handle will be held by the surgeon, it must be sterilized, not merely disinfected. Karl Storz also needs to provide the methods used to validate the recommended sterilization procedures.

x. Because the morcellator handle will be held by the surgeon, it should be sterilized, not merely disinfected. Please modify your instruction manual to remove all references to disinfection as an appropriate endpoint for reprocessing of the morcellator handle.

x. Please describe the methods used to validate each of your recommended sterilization procedures.

• *Labeling*

As requested by Dr. Dan Shultz of General Surgery, Karl Storz modified their labeling to include warnings about using a tissue bag when removing malignant tissue, as well as about not using the device on vascularized tissue (see January 26, 1995, amendment). The labeling was further modified per comments by Dr. Eugene Williams of OGDB to state that the device is contraindicated for use as a dissecting tool. The labeling needs to be modified to include specific indications for use.

x. Please modify your labeling to include indications for use.

• *Substantial Equivalence*

Karl Storz is claiming that the Steiner Electromechanic Morcellator is substantially equivalent to the Cook Tissue Morcellator (K925851). The Cook device is an AC-powered cutting tool that uses a vacuum to pull the tissue into contact with the cutting blade and then to remove the excised tissue. The Cook Morcellator was cleared in May 1993 for general surgical use.

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

Records processed under FOIA Request #2016-2105

REVIEWER RECOMMENDATION

Hold for Additional Information per phone call and FAX

Donna-Bea Tillman 2/13/95

Donna-Bea Tillman, Ph.D Date

Colin M Pollard 2/24/95

Colin M. Pollard /✓/ Concur

Chief, Ob/Gyn Devices Branch Date / / Do not concur.

Comments:

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

Records processed under FOIA Request #2016-2105

To: Donna-Bea Tillman, Ph.D.
From: Eugene W. Williams, Jr., M.D.
Subject: K946147-Steiner Morcellator
Date: February 10, 1995

Memo to the file:

In view of Karl Storz's letter to FDA, dated January 10, 1995, I find that the questions which were raised by the initial submission have been satisfactorily corrected. The only addition which should be added for the completion of this 510(K) is to #2, "...for use on vascularized tissue **and** (added word) as a dissecting tool". This 510(K) will be clinically satisfactory in its revised form.

Eugene W. Williams, Jr., M.D.
Medical Officer

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

Records processed under FOIA Request #2016-2105

DIVISION OF REPRODUCTIVE, ABDOMINAL, EAR, NOSE AND THROAT, AND RADIOLOGICAL DEVICES

MEMORANDUM OF TELEPHONE CALL

BETWEEN: Donna-Bea Tillman **DATE:** 2/10/95

AND: Marika Anderson

TITLE: Regulatory Affairs Specialist

COMPANY: Karl Storz Endoscopy America

PHONE NUMBER: (800) 421-0837 x331

FAX NUMBER:

DOCUMENT NUMBER: K946147

SUMMARY:

I told her that we had received the modified labeling that DGRD requested, and that we had two remaining questions. 1) The clinical reviewer (aka Gene) thought that the third CAUTION should be revised to: "This device is specifically contraindicated for use on vascularized tissue and as a dissecting tool". 2) Unless they could identify a predicate morcellator indicated for removal of uteri at hysterectomy, they needed to remove that indication from their 510(k) and their labeling. She said that she would discuss the matter and send me a FAX in a day or so. I told her that if I didn't receive a response by Wednesday, Feb 15, I would place the file on hold.

Signed: Donna Bea Tillman

Original to: K946147
Copy to: _____
dbtlog

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

FOIA Request #2016-4053

Karl Storz
Endoscopy-America, Inc.

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

Toll Free 800 421 0837
Fax 310 410 5527

DATE: 2-10-95

TO: Donna-Bea Tillman FAX: (301) 594-2339

FROM: Marika Anderson FAX: (310) 410-5519

OFFICE TEL: (310) 558-1500

NO. OF PAGES INCLUDING THIS COVER SHEET: 4

RE: K946147

MESSAGE:

Attached is the response to questions regarding the Steiner Morcellator. The original document will follow.

Marika Anderson

PRIVACY NOTICE

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient or the employee or agent responsible for delivering the message to the intended recipient you are hereby notified that ant dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone and return the original message to us at the above address via regular U.S. mail.

1/3

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Karl Storz Endoscopy

Karl Storz
Endoscopy-America, Inc.

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

Toll Free 800 421 0837
Fax 310 410 5527

Ref to :
95-010- MA

February 10, 1995

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

Re: K946147 (Steiner Electromechanic Morcellator and Accessories for use in Gynecology)

Dear Sir or Madam:

Additional information as requested by Donna-Bea Tillman during a telephone conversation on February 10, 1995 is provided below.

1. Modify the existing caution statement to emphasize that this device is not to be used as a dissecting tool.

The existing caution statement has been modified from" CAUTION: this device is specifically contraindicated for use on vascularized tissue as a dissecting tool." to read "CAUTION: this device is specifically contraindicated for use on vascularized tissue and as a dissecting tool". See attachment 1.

2. Provide information that demonstrates that competitor devices are used for removal/morcellation of uteri at hysterectomy or delete this intended use from the submission.

The specific intended use of removal/morcellation of uteri at hysterectomy has been deleted from this submission. The intended use of this device has been revised to " gynecological endoscopic procedures, including removal/morcellation of myomata".

If there are any questions, please contact me at the following number: 1-800-421-0837, ext. 331

Sincerely,

Marika Anderson

Marika Anderson
Regulatory Affairs Specialist

cc: T. Richards
K946147
Chron

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

Records processed under FOIA Request #2016-2105

ATTACHMENT 1

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

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

CAUTION: The use of a tissue extraction bag is recommended for the morcellation of malignant tissue or tissue suspected of being malignant and for tissue that the surgeon may consider to be harmful when disseminated in a body cavity.

CAUTION: This device is specifically contraindicated for use on vascularized tissue and as a dissecting tool.

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

Records processed under FOIA Request #2016-2105

ODE/DRAERD
REQUEST FOR CONSULTATION

FROM Donna-Bea Tillman, Ph.D

TO Eugene Williams, MD

THROUGH Robert Gatling

IDE/PMA/510(K) NO. K946147

NAME OF FIRM Karl Storz

NAME OF DEVICE Steiner Electromechanic Morcellator

DESIRED COMPLETION DATE January 30, 1995

REASON FOR REQUEST

- ■ NEW SUBMISSION
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ MODIFIED PROTOCOL
- ☐ MODIFIED DESIGN
- ☐ NEW MATERIALS
- ☐ LABELING
- ☐ MODIFIED MANUFACTURING
- ☐ OTHER _____

TYPE OF REQUEST

- ☐ ENGINEERING REVIEW
- ☐ MATERIALS REVIEW
- ☐ STERILITY REVIEW
- ☐ TOXICOLOGY REVIEW
- ■ CLINICAL REVIEW
- ☐ STATISTICAL REVIEW
- ☐ LABELING REVIEW
- ☐ OTHER REVIEW _____

COMMENTS/SPECIAL INSTRUCTIONS

Karl Storz has submitted the attached 510(k) for an Electromechanic Morcellator. The device is intended to be used during gynecologic endoscopic procedures, including removal/morcellation of myomata and uteri at hysterectomy. The device is a reusable, motor-driven tissue-cutting and removal system which includes a cannula, handle, motor, cutters, trocars, forceps, and control unit with footswitch. The 11-mm diameter cutter fits inside a 12-mm diameter cannula, and the cannula is attached to the handle (which houses the motor).

To use the device, the sharp obturator (trocar) is inserted into the lumen of the cannula, and then inserted into the abdomen. The sharp obturator is then withdrawn, and the claw forceps are inserted through the cutter. The forceps grasp the dissected tissue, and pull it to the rotating edge of the cutter, which cuts off a cylindrical block of tissue. The excised piece of tissue is then removed

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

Records processed under FOIA Request #2016-2105

through the lumen of the cutter using the forceps. This process is repeated until all the tissue has been removed.

Karl Storz has compared this device to the Cook Tissue Morcellator (K925851, copy attached). The Cook device was cleared in 1993 by General Surgery "..for the removal of dissected tissue under direct vision open surgical procedures and/or endoscopic procedures including laparoscopic and pelviscopic procedures". The major differences between the Karl Storz device and the Cook device are that

- The Karl Storz device specifically lists gynecological indications for use, while the Cook device is indicated for general purpose laparoscopy;
- The Cook device uses a vacuum to bring the tissue sample to the cutting blade, while the Karl Storz device uses forceps; and
- The Cook device is single-use, while the Karl Storz device is re-usable.

1. Does the new indication statement alter the intended therapeutic/diagnostic effect of the device, and as such constitute a new intended use?

2. Could the new technological characteristics affect the safety and effectiveness of the device? If so, is clinical data needed to demonstrate that the device performs equivalently to the predicate device?

Please feel free to identify any other clinical issues that you think need to be addressed. If you have any questions, just let me know.

Donna-Bea Tillman, Ph.D

12/29/94
Date

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

Records processed under FOIA Request #2016-2105

To: Domma-Bea Tillman, Ph.D.
From: Eugene W. Williams, Jr., M.D.
Subject: K946147 Steiner Electromechanic Morcellator
Date: January 10, 1995

Medical Review:

Intended Use & Description:

The device is a reusable motor driven tissue cutting and removal system comprised of the morcellator handle, motor, cutters, sharp obturators (trocars), claw forceps, connecting cord and multidrive control unit with footswitch. The device consists of a 12 mm diameter, 20 cm long cannula attached to the handle which houses the motor, which in turn is connected to the control unit by means of a connecting cable. The device is to be used during gynecological endoscopic surgical procedures, including removal/ morcellation of myomata and **uteri** at hysterectomy.

Substantial Equivalence:

The sponsor has utilized two marketed devices, Cook's tissue morcellator (K925851) and Dyonics Advanced Arthroscopic surgical System (K892062).

Clinical Assessment:

Morcellation is technically the division and removal, **in small pieces**, of tissue (usually tumors and bone). In gynecologic surgical procedures, particularly vaginal hysterectomy, it entails the sectioning and removal of the uterus through the vagina when, due generally to surgical misjudgement, it is too large to readily pass through the vagina. Although it (morcellation) is a old and time honored procedure, it does connote surgical misjudgement on the part of the surgeon.

Although the sponsor has utilized the aforementioned devices as predicates, clinically I differ with their assessment because the predicate devices treat tissue as described above (small pieces) and the Steiner device does not. I find this factor to be clinical significant because the tissue obtained by device in question is a better pathological specimen and may not be as prone to false readings by the pathologist who evaluates the tissue. In addition, tissue is sucked into the device on the predicates and then chopped into small pieces, not so with the Steiner device. Although these are clinically significant differences, I feel that it is pointless to argue these differences. However, it is due to these differences that I find this device clinically problematic. The other devices are utilized for morcellation after the tissue in

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question is sectioned and removed from its bed that it is morcellated. The Steiner device is more appropriately a dissecting tool which removes tissue "en-bloc". This renders the use of the device to be one where the entire specimen can not be seen when tissue is being removed from its "bed". It is partially a blind procedure. I find that this raises questions of safety. Tumors, except myomata-which are not true tumors, are very vascular. If one were to cut into and/or remove a "tumorous" growth, it is necessary to isolate and clamp/ligate all vascular connections prior to making that cut or commit to extirpation. This device does not allow the surgeon to perform this crucial step.

Although not germaine to this application, this device is quite similar to the Semms device which is used for CISH and TUMA procedures. These devices, in my clinical opinion, will need to be approved by the PMA process.

Recommendation:

Additional information is needed by this reviewer. The sponsor will need to furnish and/or delete the following:

- remove the word uteri from the intended use statement, no data has been presented to support performing a hysterec- tomy with this device;
- the sponsor needs to explain how the removal of the myomata is accomplished without damaging and/or removing uterine tissue, the design of the device is cylindrical and myomata are round;
- the predicates function by removing the tissue in question from its "bed", will this device be utilized similarly or is it to be used as described.

Eugene W. Williams, Jr., M.D.
Medical Officer

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

Records processed under FOIA Request #2016-2105

K94 6147

Karl Storz
Endoscopy-America, Inc.

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

Toll Free 800 421 0837
Fax 310 410 5527

Ref to :
95-010- MA

February 10, 1995

FDA/CDRH/OCE/DID
13 FEB 95 09:07

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

Re: K946147 (Steiner Electromechanic Morcellator and Accessories for use in Gynecology)

Dear Sir or Madam:

Additional information as requested by Donna-Bea Tillman during a telephone conversation on February 10, 1995 is provided below.

1. Modify the existing caution statement to emphasize that this device is not to be used as a dissecting tool.

The existing caution statement has been modified from" CAUTION: this device is specifically contraindicated for use on vascularized tissue as a dissecting tool." to read "CAUTION: this device is specifically contraindicated for use on vascularized tissue and as a dissecting tool". See attachment 1.

2. Provide information that demonstrates that competitor devices are used for removal/morcellation of uteri at hysterectomy or delete this intended use from the submission.

The specific intended use of removal/morcellation of uteri at hysterectomy has been deleted from this submission. The intended use of this device has been revised to " gynecological endoscopic procedures, including removal/morcellation of myomata".

If there are any questions, please contact me at the following number: 1-800-421-0837, ext. 331

Sincerely,

Marika Anderson

Marika Anderson
Regulatory Affairs Specialist

cc: T. Richards
K946147
Chron

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

Records processed under FOIA Request #2016-2105

ATTACHMENT 1

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

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

CAUTION: The use of a tissue extraction bag is recommended for the morcellation of malignant tissue or tissue suspected of being malignant and for tissue that the surgeon may consider to be harmful when disseminated in a body cavity.

CAUTION: This device is specifically contraindicated for use on vascularized tissue and as a dissecting tool.

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

Records processed under FOIA Request #2016-2105

K946147

Karl Storz
Endoscopy America, Inc.

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

Toll Free 800 421 0837
Fax 310 410 5527

Ref to :
95-007- MA

RECEIVED
27 JAN 95 10 42
FDA/CDRH/ODE/DMC

January 26, 1995

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

Re: K946147 (Steiner Electromechanic Morcellator and Accessories for use in Gynecology)

Dear Sir or Madam:

Please replace page 13 of the 510(k) submission K946147 with the revised page in attachment 1. If there are any questions, please contact me at the following number: 1-800-421-0837, ext. 331

Sincerely,

Marika Anderson

Marika Anderson
Regulatory Affairs Specialist

cc: T. Richards
K946147
Chron

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

Records processed under FOIA Request #2016-2105

ATTACHMENT 1

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

Records released under FOIA Request #2010-2705

STORZ
Karl Storz Endoscopy

DRAFT

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

CONTRAINDICATIONS: The KSEA Steiner electromechanic morcellator is contraindicated for morcellation of malignant tissue.

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

Records processed under FOIA Request #2016-2105

DRAFT

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

CAUTION: The use of a tissue extraction bag is recommended for the morcellation of malignant tissue or tissue suspected of being malignant and for tissue that the surgeon may consider to be harmful when disseminated in a body cavity.

CAUTION: This device is specifically contraindicated for use on vascularized tissue as a dissecting tool.

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

Records processed under FOIA Request #2010-2165

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

December 20, 1994

KARL STORZ ENDOSCOPY-AMERICA, INC.
600 COROPORATE POINTE
CULVER CITY, CA 90230
ATTN: MARIKA ANDERSON

510(k) Number: K946147
Received: 16-DEC-94
Product: KSE STEINER ELECTROMECHANIC MORCELLATOR

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.

The 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

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(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 and predicate device(s), or performance or clinical testing information. We cannot 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

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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 cannot complete the review of your submission until you do so.

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) 594-0639.

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.

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

Records processed under FOIA Request #2016-2105

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) 594-1190.

Sincerely yours,

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

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

Records processed under FOIA Request #2016-2105

PREMARKET NOTIFICATION (510(k)) STATUS REQUEST

TO: 510(k) Status Coordinator
Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health, FDA
5600 Fishers Lane
Rockville, MD 20857
USA
Fax Number: (301) 443-8818

Please provide the status of the 510(k) identified below. Please send the information to the requester identified in section B by (check one):

____ fax
____ mail

A. Sponsor Information:

1. Name of 510(k) sponsor: _____

2. Sponsor's mailing address: _____

_____

_____

B. Requester information:

1. Request name: _____

equester affiliation with sponsor: _____

3. Requester mailing address: _____

_____

_____

4. Request fax number (if applicable): _____

5. Requester telephone number: _____

C. 510(k) information:

1. Product name: _____

2. 510(k) number: _____

3. Date logged in by Office of Device Evaluation (ODE) (as identified in acknowledgment letter from ODE): _____

Name of contact person identified on firm's 510(k) submission: _____

.....

ertify that the above information is accurate and truthful to the of my knowledge.

(Rev:2)

_____
Requester signature

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

Records processed under FOIA Request #2016-2105

STORZ
Karl Storz Endoscopy

Karl Storz
Endoscopy America, Inc.

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

Toll Free 800 421 0837
Fax 310 410 5527

K946147

December 14, 1994

FDA/CDRH/OCE/DMC

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

Re: 510(k) Notification for Karl Storz Endoscopy-America, Inc. Steiner Electromechanic Morcellator and Accessories for use in Gynecology

Attn: Division of Reproductive, Abdominal, Ear, Nose, Throat and Radiological Devices (DRAERD)

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FDA Act), Karl Storz Endoscopy-America, Inc. (KSEA) hereby submits this notification for its Steiner Electromechanic Morcellator and Accessories, intended for use during endoscopic surgical procedures. This notification is submitted by KSEA, in response to FDA's letter to medical device manufacturers, dated May 17, 1993, requiring premarket clearance of endoscopic accessories.

Per the requirements outlined in the Safe Medical Devices Act of 1990, KSEA has enclosed a summary of safety and effectiveness in this premarket notification.

KSEA respectfully requests that the contents of this notification be considered confidential per 21 CFR 20.61.

The KSEA Steiner Electromechanic Morcellator is a motorized, reusable surgical device intended for use by qualified surgeons during gynecological endoscopic surgical procedures, including removal/morcellation of myomata and uterus at hysterectomy.

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

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The Table [illegible] the [illegible] [illegible] which contains the information required by [illegible]

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

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

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

510(k) Number &
Device Name Steiner Electromechanic Morcellator

Company Karl Storz Endoscopy-America, Inc.

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	—	—
Certification - identical material/formulation	—	—	N
6. Performance data: Bench data	—	—	N
Animal data	—	—	N
Clinical data	—	—	N
7. Sterilization information	X	—	—
8. Software validation & verification	—	—	N
9. 510(k) summary or statement	X	—	—
10. If Class III, Class III Certification & Summary	—	—	N
11. If kit, kit certification	—	—	N

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

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I. Name of Device

Proprietary Product Name	KSEA Steiner Electromechanic Morcellator
Common/Usual Name	Tissue Morcellator
Classification Name:	Accessory to Endoscope

II. Establishment Registration Number

KSEA is the initial importer of these instruments. The establishment registration number for KSEA is 2020550.

III. Class Of Device

The FDA has classified instruments of this type and intended use in 21 CFR 876.1720 and 884.1690 as Class II devices, under the product categories of Gynecologic Laparascope and Accessories and Hysteroscope and Accessories, respectively.

IV. Performance Standards

No performance standards or special controls have been established by FDA under section 514 of the FDC Act.

V. Labeling

Representative draft literature for the KSEA Steiner Electromechanic Morcellator is included in Enclosure 1 of this submission.

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

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VI. Description of the Device and Intended Use

The KSEA Steiner Electromechanic Morcellator is a motorized, reusable surgical device. The device is intended for use by qualified surgeons during the endoscopic surgical procedure. As described more fully below, the KSEA Steiner Electromechanic Morcellator presented in this notification is intended to be used during gynecological endoscopic surgical procedures, including removal/morcellation of myomata and uteri at hysterectomy. KSEA representative draft labeling is provided in Enclosure 1. Instructions for cleaning and disinfection may be found in Enclosure 3. Supporting literature for the use of these accessories to endoscopes is provided in Enclosure 4.

The Steiner Electromechanic Morcellator is a reusable motor driven tissue cutting and removal system comprised of the Morcellator handle, motor, cutters, sharp obturators (trocars), claw forceps, connecting cord and multidrive control unit with footswitch. The device consists of a

(b)(4)

[redacted]

The control unit features power switch, speed range control, pilot lights that indicate the direction of rotation, connection ports for the cables to the footswitch and morcellator motor. The motor connector cord is an insulated, two conductor, nonshielded cable with miniature RCA type connectors with gold leads. The control unit designs comply with applicable IEC 601-1 standards for medical devices of this nature. The type and degree of protection against electrical shocks complies with UL 544 standards.

The sharp obturator is inserted through the silicone rubber gasket on the morcellator handle and into the lumen of the cutter. The morcellator is inserted directly into the abdomen, the sharp obturator is withdrawn from the morcellator and the clawed forceps are inserted through the cutter. The forceps grasp the dissected tissue to be removed and pull it to the rotating cutting edge of the morcellator which cuts off a cylindrical block of tissue. This excised piece of tissue is removed from the cutter lumen with the forceps. This process is repeated until the entire piece of tissue has been morcellated and removed. The KSEA Steiner electromechanic morcellator is intended to be used during gynecological endoscopic surgical procedures, including removal/morcellation of myomata and uteri at hysterectomy.

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

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VII. Substantial Equivalence

A. KSEA Steiner Electromechanic Morcellator

The KSEA Steiner Electromechanic Morcellator is substantially equivalent to devices currently legally marketed by Cook and Dyonics and to devices marketed by KSEA prior to May 28, 1976. The KSEA Steiner Electromechanic Morcellator presented in this notification is intended to be used during gynecological endoscopic surgical procedures, including removal/morcellation of myomata and uteri at hysterectomy. A comparison of device characteristics is presented in the Substantial Equivalence Table, which is provided in Part B of this section. KSEA representative draft labeling is provided in Enclosure 1. Marketing literature for the currently marketed predicate devices is provided in Enclosures 2.

The Steiner Electromechanic Morcellator is a reusable motor driven tissue cutting and removal system comprised of the morcellator handle, motor, cutters, sharp obturators (trocars), claw forceps, connecting cord and multidrive control unit with footswitch. The device consists of a

(b)(4)

[redacted]

The control unit features power switch, speed range control, pilot lights that indicate the direction of rotation, connection ports for the cables to the footswitch and morcellator motor. The motor connector cord is an insulated, two conductor, nonshielded cable with miniature RCA type connectors with gold leads. The connector cord is 385 cm in length. The control unit design complies with applicable IEC 601-1 standards for medical devices of this nature. The type and degree of protection against electrical shocks complies with UL 544 standards.

The sharp obturator is inserted through the silicone rubber gasket on the morcellator handle and into the lumen of the cutter. The morcellator is inserted directly into the abdomen, the sharp obturator is withdrawn from the morcellator and the clawed forceps are inserted through the cutter. The forceps grasp the dissected tissue to be removed and pull it to the rotating cutting edge of the morcellator which cuts off a cylindrical block of tissue. This excised piece of tissue is removed from the cutter lumen with the forceps. This process is repeated until the entire piece of tissue has been morcellated and removed. The KSEA Steiner electromechanic

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

morcellator and accessories is intended to be used during gynecological endoscopic surgical procedures, including removal/morcellation of myomata and uteri at hysterectomy.

The KSEA Steiner Electromechanic Morcellator is substantially equivalent to predicate devices legally marketed by Cook (K925851). The Cook Tissue Morcellator is a sterile, single use, disposable motorized tissue cutting and removal device with a reusable motor assembly and power supply. This device is comprised of a cannula, morcellator blade, morcellator body, tissue collection chamber, vacuum control valve, motor assembly, power supply with footswitch. The cutter is a circumferentially sharpened tube 11 mm in diameter and 13.5 cm in length which fits inside the cannula. The cutting edge is rotated at a fixed rate of 4,000 to 5,000 rpm via use of the footswitch. All body contact portions of the Cook Tissue Morcellator are manufactured from surgical grade stainless steel. The Cook power supply assembly features a power switch.

The Cook tissue morcellator is inserted through an incision into the abdomen, the vacuum and morcellator blade are activated and the device is advanced into the tissue to be morcellated. The vacuum pulls the tissue into contact with the morcellator blade and subsequently into the morcellator cannula. The excised tissue is removed by vacuum from the cutter lumen into the tissue collection chamber. The Cook Tissue morcellator is intended to be used for the removal of dissected tissue under direct vision open surgical procedures and/or endoscopic procedures including laparascopic and pelviscopic procedures.

The KSEA Steiner Electromechanic Morcellator is substantially equivalent to predicate devices legally marketed by Dyonics (K892062). The Dyonics arthroscopic surgical system is a reusable motorized tissue cutting and removal device with motor drive and control unit. This device is comprised of a cannula, morcellator blade, motor assembly and power supply with footswitch. The cutter is a circumferentially sharpened tube 3.5 - 5.5 mm in diameter; length is unavailable. The cutting edge is rotated at an unknown rate via use of the footswitch. All body contact portions of the Dyonics device are manufactured from surgical grade stainless steel. The control unit features include a power switch, speed control and connection ports for the cables to the footswitch and the morcellator motor drive.

The Dyonics tissue morcellator is inserted through an incision into an articular cavity, the vacuum and morcellator blade are activated and the device is advanced into the soft tissue to be morcellated. The vacuum pulls the tissue into contact with the morcellator blade and subsequently into the morcellator cannula. The excised tissue is removed by vacuum from the cutter lumen into an outside tissue collection container. The Dyonics arthroscopic surgical system is indicated for removal of damaged tissue in articular cavities during arthroscopic procedures. Despite the fact that the predicate device is intended for use in arthroscopy and the KSEA device is intended for use in gynecology , both devices have the same intended use of cutting and removing tissue from the body.

The KSEA obturators used with the Steiner Electromechanic Morcellator are substantially equivalent to predicate devices marketed by KSEA prior to May 28, 1976. The pre-1976 predicates were available in diameters ranging from 7 to 11 mm, with pyramidal tips and were

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manufactured from surgical grade stainless steel These devices were intended to create an incision into the patients body to allow insertion of cannula prior to endoscopic gynecologic surgery

The KSEA claw forceps used with the Steiner Electromechanic Morcellator are substantially equivalent to the KSEA claw forceps that have been previously cleared by the 510(k) process. Both devices are 10 mm in diameter, 36 cm in length with 2 x 3 teeth and jaws made of series 420 surgical grade stainless steel. Both of these devices are intended for use in gynecologic procedures, however, the forceps in this submission are specifically intended for use with the Steiner morcellator.

The KSEA Steiner Electromechanic Morcellator and the predicate morcellator devices are similar in body contact materials and design so no new issues of safety and effectiveness are raised. All of the devices are motorized, foot pedal controlled and feature a surgical grade stainless steel cannula with a rotary cutting blade. The KSEA subject device and the Cook predicate device have similar dimensions. The Dyonics device has a smaller diameter due to the fact that this device is designed to access small areas within joints. There are no safety issues regarding potential hazards involving the use of vacuum for the KSEA subject device as there are for the Cook and Dyonics device. The KSEA and Cook devices have the same intended use of removing and morcellating tissue during endoscopic procedures. Although the KSEA and Dyonics devices are intended for use in different anatomical locations, both devices have the same intended use of morcellating and removing tissue from the surgical site during endoscopic procedures.

The KSEA sharp obturators for use with the Steiner Electromechanic Morcellator are similar in body contact materials, dimensions and design to the KSEA Pre-1976 predicate trocars so no new issues of safety and effectiveness are raised. These devices have the same intended use of creating an incision into the patients body to allow insertion of cannula prior to endoscopic gynecologic surgery.

The KSEA claw forceps for use with the Steiner Electromechanic Morcellator are identical in body contact materials, dimensions and design to the KSEA forceps so no new issues of safety and effectiveness are raised. These devices both are intended for use in endoscopic gynecologic surgery.

B. Substantial Equivalence Table

KSEA has compared its subject endoscopes with similar devices that have been manufactured by several other companies and cleared by the 510(k) notification process. This comparative information is provided in this section. Substantial equivalence is supported by the following data.

KARL STORZ STEINER ELECTROMECHANIC MORCELLATOR AND EQUIVALENT PRODUCTS

MANUFACTURER AND DEVICE	DIMENSIONS	TISSUE REMOVAL METHOD	TYPE OF CUTTER	MATERIAL	INTENDED USE
Karl Storz Steiner Electromechanic Morcellator	**13 mm diameter, 20 cm length**	**Mechanical**	**Rotary**	**Series 303 or 304 Surgical Grade Stainless Steel**	**Morcellation and removal of tissue during gynecologic endoscopic procedures**
Cook (K925851) Tissue Morcellator	10 mm diameter, 14 cm length	Vacuum	Rotary	Surgical Grade Stainless Steel	Morcellation and removal of dissected tissue under direct vision open surgical procedures and/or endoscopic procedures including laparascopic and pelviscopic procedures
Dyonics (892062) Advanced Arthroscopic Surgical System	3.5 - 5.5 mm diameter, length unavailable	Vacuum	Rotary	Surgical Grade Stainless Steel	Reset damaged tissue and remove extraneous matter in articular body cavities
Karl Storz Sharp Obturators	**10 mm diameter**	**N/A**	**N/A**	**Series 303 or 304 Surgical Grade Stainless Steel**	**To create incision to allow insertion of cannula prior to endoscopic gynecologic surgery**
Karl Storz Pre-1976 Trocars	7 - 11 mm diameter	N/A	N/A	Same	Same
Karl Storz Claw Forceps	**10 mm diameter, 36 cm length**	**N/A**	**N/A**	**Series 420 surgical grade stainless steel**	**To grasp tissue during gynecologic endoscopic procedures**
Karl Storz Claw Forceps (K935070)	10 mm diameter, 36 cm length	N/A	N/A	Series 420 surgical grade stainless steel	To grasp tissue during gynecologic endoscopic procedures

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

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VIII. Additional Information

A. Sterilization and Cleaning

The KSEA Steiner Electromechanic Morcellator is sold non-sterile and is reusable. KSEA recommends that before use, reuse and sterilization, meticulous cleaning of these instruments should be performed by the user. Additional supporting information for the sterilization of the KSEA Steiner Electromechanic Morcellator and accessories is provided in Enclosure 1.

B. Biocompatibility

The working elements of the KSEA Steiner Electromechanic Morcellator and accessories come into contact with the patient for brief periods of time. All components which come into body contact are constructed of surgical grade stainless steel. The material(s) used in these instruments is commonly used in medical devices for a wide range of applications and have a long history of biocompatibility for human use.

C. Scientific Journal Articles

Scientific journal articles and additional supporting literature is provided in Enclosure 4.

IX. Confidentiality

The existence of this submission and certain information contained within may be trade secret, or confidential commercial or financial information within the meaning of 21 CFR 20.61. KSEA has maintained the existence of this submission as confidential commercial information and has not disclosed this submission to anyone except its employees, consultants, and law firms. KSEA respectfully requests that the FDA consider the contents of this submission confidential and requests that FDA consult with KSEA prior to releasing any information contained in this submission.

X. 510(k) Summary of Safety and Effectiveness Information

In response to the Safe Medical Devices Act of 1990, a 510(k) Summary of Safety and Effectiveness Information is provided in Enclosure 5.

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

XI. Contact Person

We believe that substantive information necessary to enable FDA to find the products subject of this notification substantially equivalent with legally marketed devices has been provided in this document. In the event that additional clarification or information is needed, please contact Marika Anderson, Regulatory Affairs Specialist, KSEA, at 600 Corporate Pointe, Culver City, CA. 90230; telephone: (310) 558-1500 Ext. 331, FAX: (310) 410-5519.

Best regards,

Marika Anderson

Marika Anderson
Regulatory Affairs Specialist

Talk to Gene

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KARL STORZ REPRESENTATIVE DRAFT LITERATURE

DRAFT

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

CONTRAINDICATIONS: The KSEA Steiner electromechanic morcellator is contraindicated for morcellation of malignant tissue.

STEINER **Electromechanic Morcellator**
for Surgical Laparoscopy.

KARL STORZ — ENDOSKOPE

STEINER **Electromechanic Morcellator for Surgical Laparoscopy.**

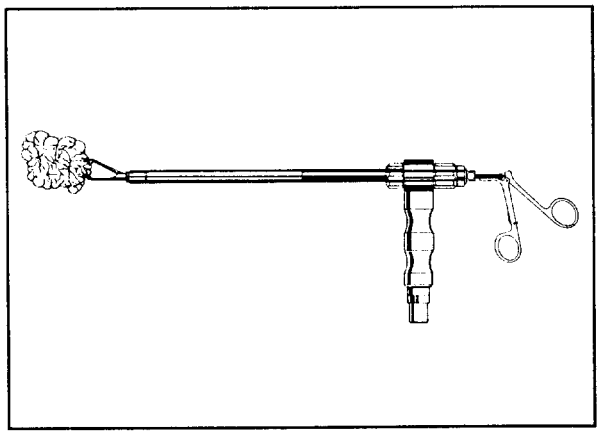
Endoscopic interventions which are necessary to remove large sections of tissue, such as myomata still represent a challenge for minimally invasive surgery. Although several extraction techniques are now available specifically for removing large tissue quantities, this procedure is usually very time-consuming and often requires enlargement of the incision or even an additional incision

In contrast, the Electromechanic Morcellator makes it easy to remove even relatively large sections of tissue from the abdomen in only a few minutes through the existing incisions.

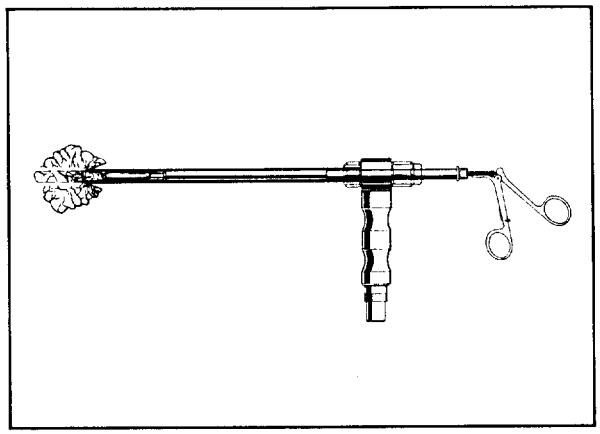
The Electromechanic Morcellator consists of a motor-driven cutting tube which can be inserted direct into the abdomen without an additional trocar cannula. The speed of rotation is preselectable in 3 steps and can be triggered via a footswitch. There is the option of clockwise, counterclockwise and oscillating rotation.

Clawed forceps for gripping the tissue to be extracted are inserted into the abdomen through the cutting tube. If the forceps are then pulled back, pressing the tissue against the cutting edge of the rotating morcellator, a cylindrical block of tissue can be cut out and removed through the tube by applying a measured pulling force and, if necessary varying the speed and direction of rotation. In this way even large tissue quantities can be removed within few minutes. The excellent cutting effect prevents damage to the architecture, so that reliable histological examinations are also possible.

DRAFT



The tissue is gripped by forceps passed through the cutting tube.



The tissue is pressed against the rotating cutting tube by pulling back the forceps and in this way a cylindrical section of tissue is cut out, which can then be easily extracted.

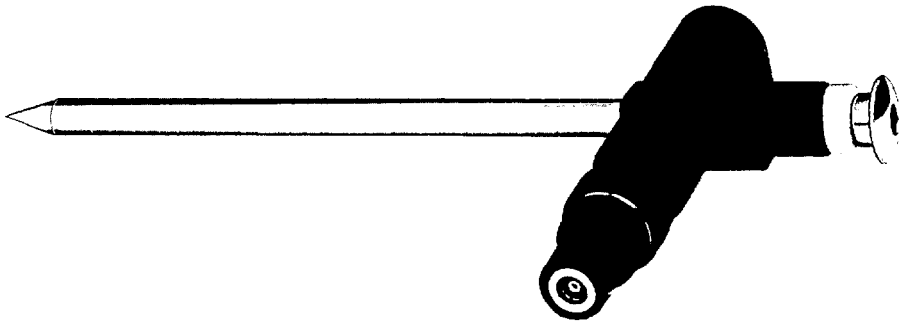
STEINER **Electromechanic Morcellator**

for Surgical Laparoscopy,
size 12 mm.

KARL STORZ — ENDOSKOPE

For use with trocars, size 13 mm.

DRAFT



26712011 STEINER **Electromechanic Morcellator, consisting of:**

- **26**712031 1 **Morcellator Handle,** 300 rpm. max.
- **20**712030 1 **Motor.**
- **26**712040 2 **Cutters**
- **26**712041 1 **Obturator** with conical tip.
- **26**712042 1 **Obturator** with pyramidal tip.
- **26**712070 1 **Connecting Cord** for connecting the MULTIDRIVE control unit with motor **20**712030.
- 30422 FS 1 **Take-apart® Claw Forceps,** 2 × 3 teeth, consisting of:
  - 30552 **Metal-Handle.**
  - 30540 **Outer Tube.**
  - 30420 FS **Claw Forceps.**

1-94

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MULTIDRIVE Control Unit

for use with STEINER Electromechanic Morcellator.

KARL STORZ — ENDOSKOPE

Special features:

- Speed of rotation preselectable in 3 steps.
- 3 footswitch functions:
  clockwise, counterclockwise and oscillating rotation (clockwise-counterclockwise).
- The modular design makes it easy to clean and sterilize the single components.

Specifications:

Dimensions:	305 mm × 105 mm × 233 mm (w × h × d).
Weight:	approx. 5 kg.
Design:	according to IEC 601-1.

DRAFT

20712001 **MULTIDRIVE Control Unit,**
power supply: 100–240 VAC, 50/60 Hz
consisting of:

400 A	1	**Mains Cord.**
20712020	1	**MULTIDRIVE Unit.**
20010430	1	**Two-Pedal Footswitch.**

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000016

Instruction Manual – preliminary –	STORZ KARL STORZ – ENDOSKOPE	Date: September 94

DRAFT

Instruction Manual

STEINER Electromechanic Morcellator
Model 267120 11

MULTIDRIVE Control Unit
Model 207120 20

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Instruction Manual – preliminary –	STORZ KARL STORZ – ENDOSKOPE	Date: September 94

Operating elements, displays, connectors and their uses

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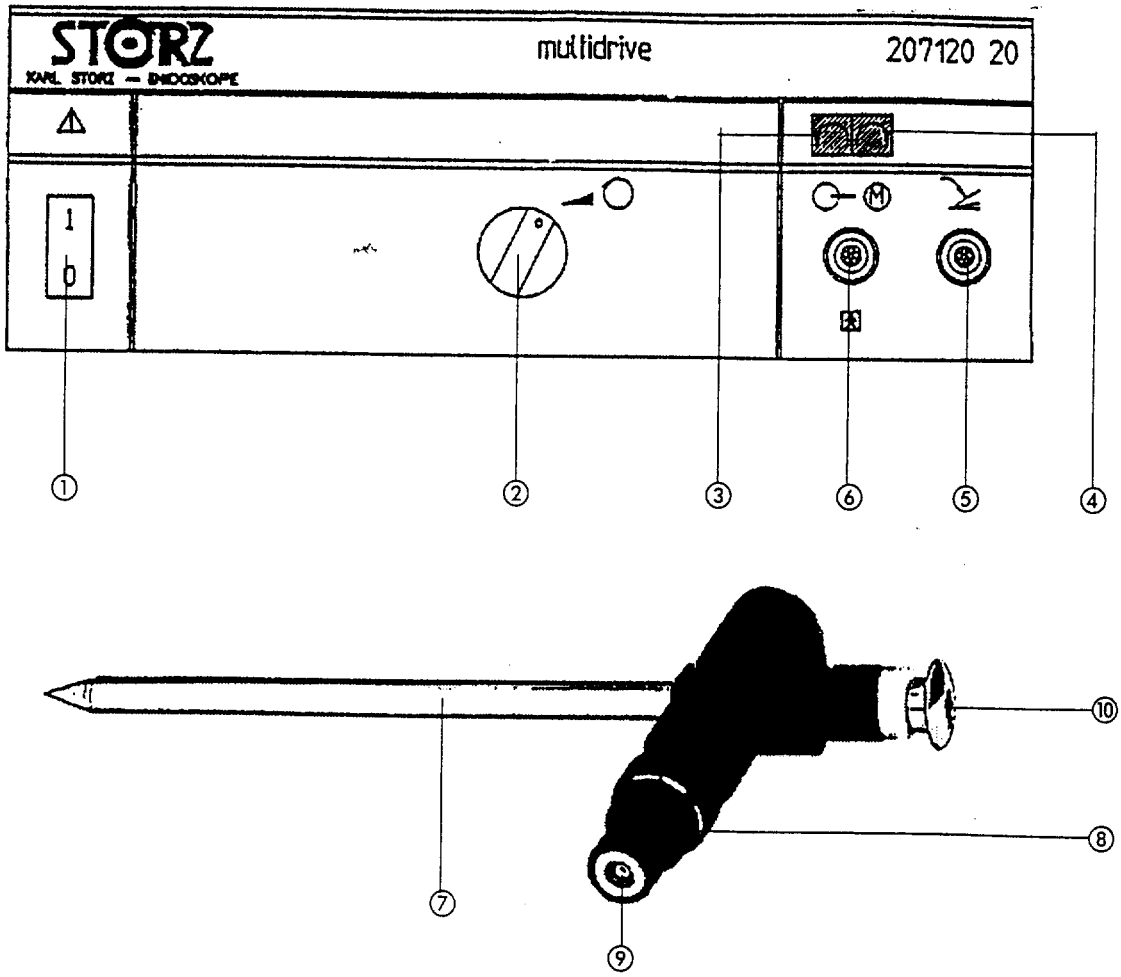


① Power switch
② Speed range control
③ Pilot lamp for counterclockwise rotation
④ Pilot lamp for clockwise rotation
⑤ Connector for footswitch
⑥ Connector for handle
⑦ Morcellator
⑧ Handle with motor inserted
⑨ Connector for connecing cable to the control unit
⑩ Obturator

DRAFT

Cautions:

- DANGER: Risk of explosion if used in the presence of flammable anesthetics
- CAUTION: To reduce the risk of electrical shock, refer servicing to qualified service personnel
- CAUTION: Cutting tube is sharp-edged. Damage to tissue can also result when cutting tube is not activated. Insert cutting tube only under visual observation.
- Read the instructions carefully before operating the unit
- Keep out of reach of patients

Installation and operation of the unit

1. Connect power cord. Insert the power cord into power connector as far as it will go. Connecting the instrument to the power line should only be carried out outside potentially explosive locations.

DRAFT

2. Plug the footswitch cable into socket ⑤ as far as it will go.

3. Push the motor into the morcellator handle ⑧ until it locks into place.

4. Connect the motor ⑨ to the control unit using the connecting cable supplied.

5. Switch on power switch ①.

6. Set the desired speed range on switch ②.

7. The direction of rotation is controlled with the footswitch:

Left pedal:	counterclockwise (pilot lamp ③ illuminates)
Right pedal:	clockwise (pilot lamp ④ illuminates)
Left and right pedal:	Oscillation (pilot lamps ③ and ④ illuminates alternately)

In the oscillation mode the direction of rotation changes 2 times within a second. It is advisable to switch to this operating mode whenever the morcellator has jammed.

Note: To prevent the motor from overheating, the oscillation mode is limited to a period of 5 seconds.

Inserting the morcellator

1. Insert the cutting tube into the abdomen.

2. To remove tissue, a claw forceps is intoduced via the cutting tube.

3. The tissue is pressed against the rotating cutting tube by pulling back the forceps and in this way a cylindrical section of tissue is cut out, which can then be easily extracted.

DRAFT

Changing the cutting knife

Caution: Always pull out the power plug beforehand!

1. Unscrew the black screw cap at the proximal end of the handle.

2. Remove the larger screw cap at the distal end of the handle. The cutting knife can now be pulled out.

3. Insert the new cutting knife. Then reassemble the handle in reverse sequence.

Fuse replacement

Caution: Always pull out the power plug beforehand!

1. Remove the power fuse holder with a screwdriver or other tool.

2. Insert new fuses of the appropriate rating.

3. Replace power fuse holder.

Cleaning and care of the unit

Caution: Always pull out power plug before cleaning.

The instrument surface should be cleaned with a mild cleaning agent or disinfectant. Do not allow any cleaning liquid to get into the instrument.

The morcellator handle and the motor may be steam or gas sterilized, or disinfected in cold antiseptic solutions.

The connecting cord may be steam or gas sterilized.

Do not disinfect the connecting cord in antiseptic solutions.

Manufacturer's warranty

For **one** year as of delivery to the end customer we agree to replace the goods free of charge if proof can be provided of faulty materials or faulty workmanship. In doing so we cannot accept to bear the cost of transportation or the risk of shipment. The warranty referred to in § 3 of our Standard conditions of Business shall apply.

Opening the equipment or performance of any repairs or modifications of the equipment by unauthorized persons shall relieve us of any liability for its performance. Any such opening, repair or modification during the warranty period shall void all warranty.

DRAFT

Specifications (MULTIDRIVE Control Unit)

Power supply voltage:	100/120/230/240 VAC
Power frequency:	50/60 Hz
Oscillation frequency range	80 – 390 rpm
Operating temperature:	10 °C – 40 °C (50 – 104 °F)
Storing temperature:	0 °C – 60 °C (32 – 140 °F)
Dimensions:	305 mm x 109 mm x 271 mm (w x h x d)
Weight:	5.0 kg
Design:	According to IEC 601-1

Equipment classification:

Degree of waterproofing:
Drip-proof per IPX 1

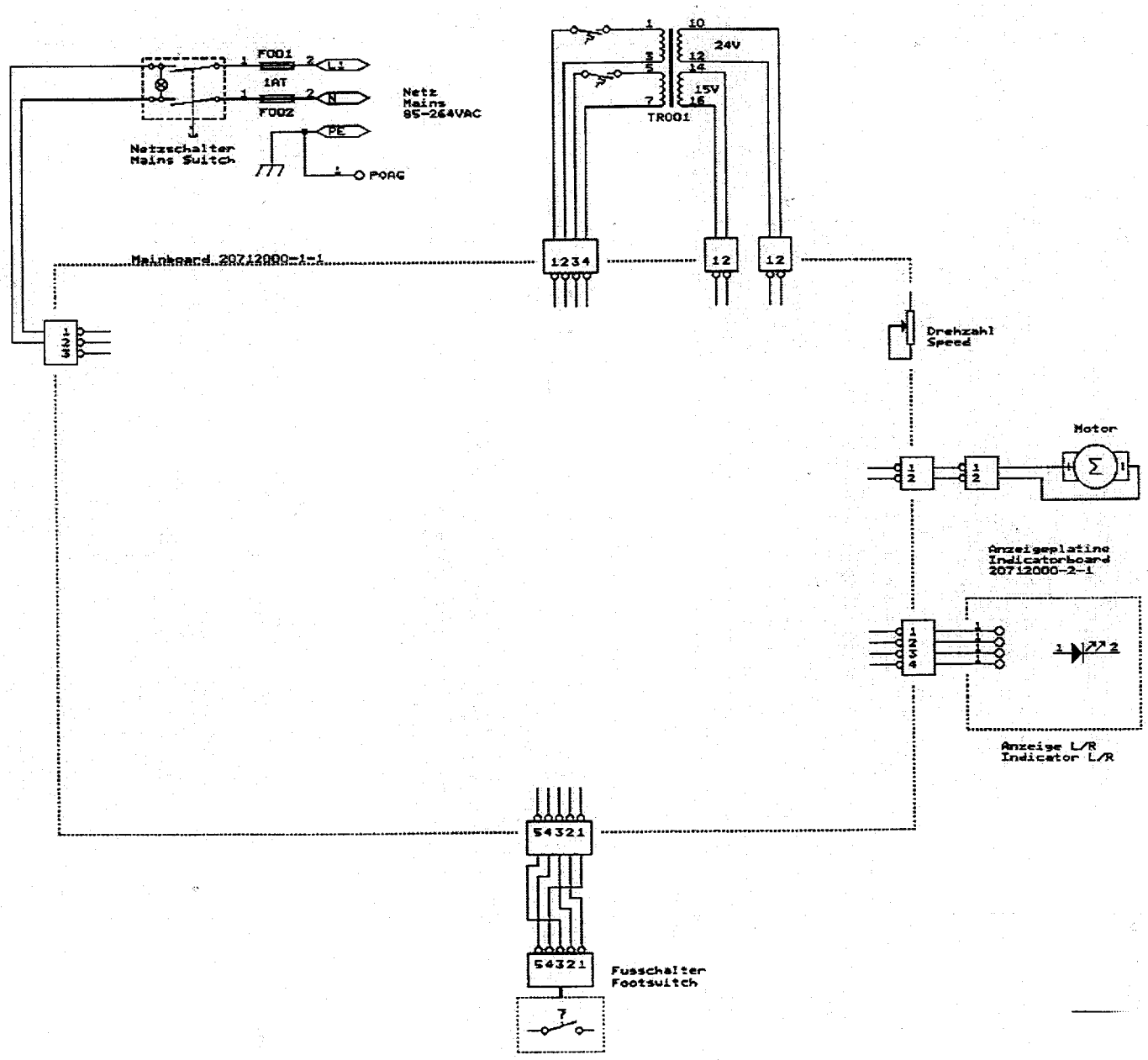
Type of protection against electric shocks:
Protection class 1

Degree of protection against electric shocks:
BF-type instrument

The type and degree of protection against electrical shocks complies with UL 544 standards

General circuit diagram

DRAFT



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PREDICATE LITERATURE

COOK

Cook® Tissue Morcellator™

Description:

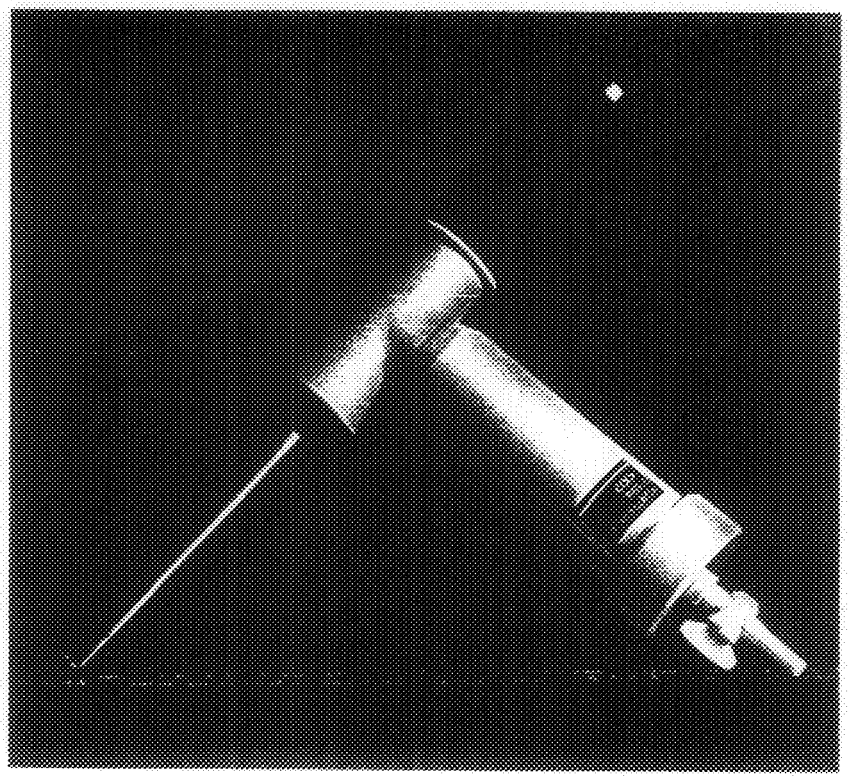
Morcellator body assembly with stainless steel cutting cannula and vacuum control valve

Cook® Series 1 Tissue Morcellator™ Power Supply Assembly includes Series 1 power supply with cord, foot switch with motor cable, and tissue morcellator motor assembly in a storage case; non-sterile

The Cook® Tissue Morcellator™ is used for the morcellation and removal of dissected tissue under direct vision, open surgical procedures, and/or endoscopic procedures when used in conjunction with the LapSac™.

The action of the Morcellator™ is based upon a combination of a circumferentially sharpened cutting cannula (patent pending) and a hospital house vacuum. The stationary outer sheath has an angular opening which protects the LapSac™ (organ entrapment system featured on next page) from contacting the inner cutting cannula blade.

The Cook® Tissue Morcellator™ has an electric motor which drives the inner cutting cannula at a fixed rate of 4,000 to 5,000 r.p.m. The motor is reusable, non-sterile, and does not come into contact with tissue or body fluids. The collection chamber filter is bonded to the vacuum control valve/handle. The handle is capable of holding 184 ml of morcellated tissue without interruption to empty.



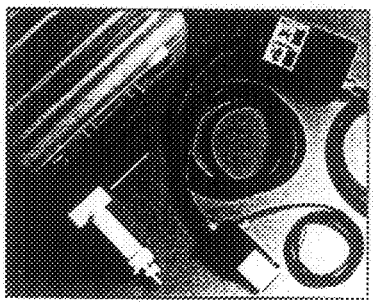
The Morcellator™ can be an effective tool in the reduction of surgical trauma related to the removal of dissected tissue.

The Cook® Tissue Morcellator™ is supplied sterile in peel-open packages and is intended for one-time use.

Note: The Cook® Series 1 Tissue Morcellator™ Power Supply Assembly must be ordered separately.

For order information see page 31.

Patent Pending



Cook® Tissue Morcellator™, power supply assembly and storage case.

COOK® TISSUE MORCELLATOR™

Operators Manual

COOK UROLOGICAL INCORPORATED
A COOK GROUP COMPANY
1100 West Morgan Street P.O. Box 227
Spencer, Indiana 47460 U.S.A.
Phone: 812 829-4891 Telefax: 812 829-2022
Toll Free: 800 457-4448

COOK OB/GYN®
A DIVISION OF COOK UROLOGICAL INC.
1100 West Morgan Street P.O. Box 271
Spencer, Indiana 47460 U.S.A.
Phone: 812 829-6500 Telefax: 812 829-2022
Toll Free: 800 541-5591

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MRCL693

CAUTION: The Cook® Tissue Morcellator™ is intended for use by physicians trained and experienced in techniques for tissue morcellation.

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Cook® Tissue Morcellator™ Body Assembly

Cook Urological®
Order Number: 410010

Cook Ob/Gyn®
Order Number: KCTM-410010

The Cook® Tissue Morcellator™ Body Assembly is supplied sterile in peel-open packages and is intended for one-time use.

Description:
Polyvinylchloride morcellator and tissue collection chamber with vacuum control valve and stainless steel cutting cannula assembly

Stainless steel collection chamber filter

Polyurethane sterility sleeve 200 cm long

Cook® Series 1 Tissue Morcellator™ Power Supply Assembly

Cook Urological®
Order Number: 410000

Cook Ob/Gyn®
Order Number: KCTM-410000

Components: (Supplied non-sterile)

Cook® Series 1 Power Supply
- Line voltage: 120 V AC
- Line Frequency: 60 Hz
- Line Current: 1 A
- Output: 24 V DC, 100 VA
- Output is electrically isolated

Power cord

Foot switch

Motor cable with waterproof connector

Cook® Series 1 Tissue Morcellator™ Motor Assembly

Contraindications:

The Cook® Tissue Morcellator™ is contraindicated for the morcellation of bone and for use in liposuction procedures.

Precautions and Warnings:

The Cook® Tissue Morcellator™ should be used during laparoscopic, pelviscopic and percutaneous procedures only by physicians with adequate training in these procedures.

A comprehensive preoperative medical history and physical examination are suggested. Radiographic evaluation and laboratory tests may be included.

The Cook® Tissue Morcellator™ will cut and aspirate tissue when vacuum is applied in combination with blade rotation and direct contact with tissue. **WARNING: Do not place the blade in contact with tissue which is not intended to be morcellated.**

Direct contact of the rotating cutting edge of the blade with metal (e.g.: cannula, endoscope, or other instruments) can cause damage to the morcellator blade. If such contact should occur, the entire morcellator body assembly should be discarded and a new unit substituted. Replacement blades are not available for the morcellator.

Patent Pending

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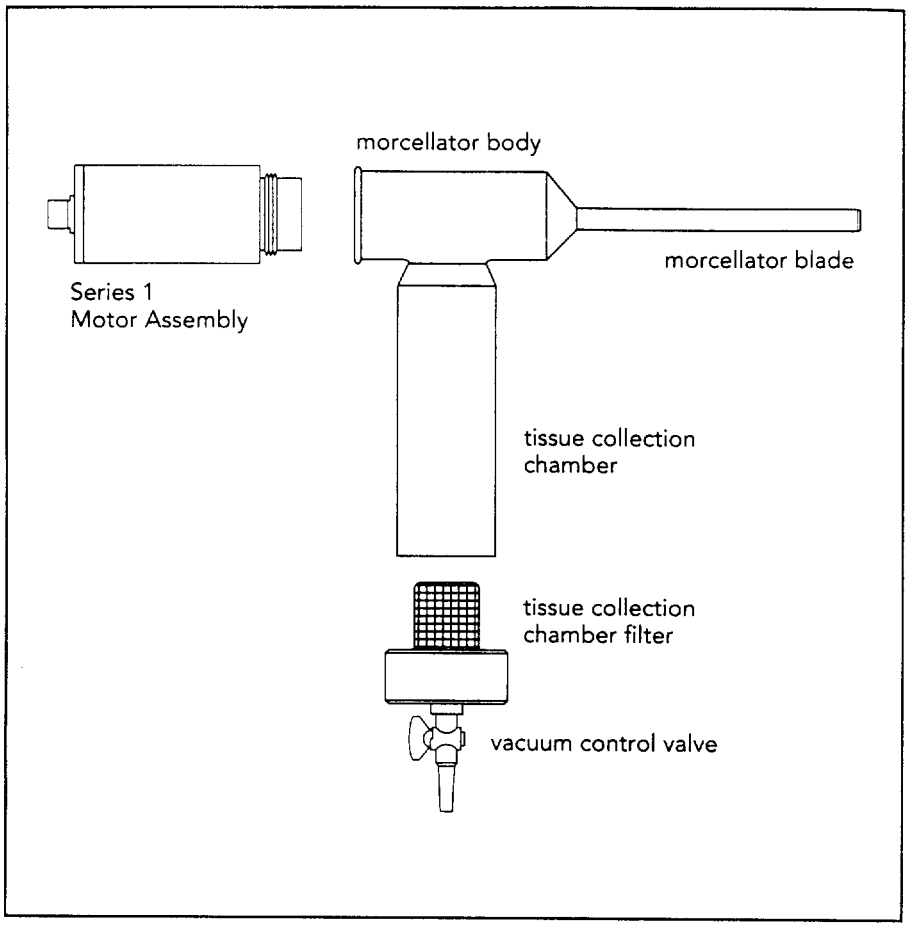


The Cook® Tissue Morcellator™ rotary scalpel is used for morcellation and removal of dissected tissue under direct vision, open surgical procedures, and/or endoscopic procedures when used in conjunction with the LapSac™.

Operator Instructions:

DANGER: Risk of explosion. Do not operate the morcellator in the presence of flammable anesthesia and other volatile materials.

WARNING: Electrical shock hazard. Do not attempt to remove the cover from the power supply assembly, or disassemble the morcellator motor.

If the power supply or motor fail to perform properly, contact Customer Service (800 457-4448 or 800 541-5591) for a return authorization.

In the event that you must return the power supply assembly for service, it should be cleaned and packed in the original case for shipping.

Assembly:

1. In the sterile field, remove the morcellator body assembly from the sterile packaging.

n the sterile field, attach the non-rile motor assembly to the morcellator body, taking care to avoid entangling the sterility sleeve in the motor threads.

3. Attach the non-sterile motor cord to the motor assembly. **CAUTION: The Series 1 Motor Assembly is intended for use with a Cook® Series 1 Power Supply only. Do not attempt to substitute other power supplies.**

4. Pull the sterility sleeve over the motor and cord.

5. Maintaining the sterile field, attach vacuum tubing to the vacuum control valve on the morcellator. Connect vacuum tubing to wall suction (20 to 28 in. Hg).

6. Plug the power cord to a hospital grade receptacle and position the foot pedal switch appropriately.

7. The device is now ready for use.

Operation:

1 The circuit breaker, located on the ver Supply Assembly, must be in the on position to power the morcellator. The circuit breaker will switch to the off position in the event of a fault.

2. Open the vacuum control valve on the morcellator body.

CAUTION: Direct application of vacuum to an insufflated peritoneum will result in loss of insufflation medium. Morcellator must be used in conjunction with a LapSac™ during endoscopic procedures. Not recommended for use with other tissue isolation products.

3. Depress foot pedal to activate morcellator blade. The foot pedal is a threshold switch; morcellator blade speed is constant. To stop blade, release foot pedal switch. **NOTE: The vacuum control valve and foot pedal can be turned on and off at the physician's discretion throughout the procedure.**

4. Advance morcellator cannula directly into tissue to be morcellated. To achieve optimal morcellation use measured, methodical strokes in favor of forcibly driving the sheathed rotary scalpel into tissue. Continue until desired morcellation is complete.

WARNING: The LapSac™ can be cut if manual tension is not maintained. The assisting surgeon must maintain manual tension to prevent folds of the LapSac™ from being drawn into the morcellator. The LapSac™ should be monitored by video throughout the morcellation.

5. To remove tissue from collection chamber:

a. Close vacuum control valve.

b. Remove base from the tissue collection chamber.

Disassembly:

1. Turn off wall suction.

2. Unplug power cord from wall outlet.

3. Remove the sterility sleeve and disconnect the motor cable from the morcellator motor.

4. Disconnect the vacuum tube from the vacuum control valve.

5. Remove the motor from the morcellator body.

6. Dispose of the morcellator body properly.

Morcellator Motor and Power Supply Assembly Cleaning Instructions:

CAUTION: Do not attempt to sterilize the motor or power supply assembly by steam autoclave, ethylene oxide gas (ETO), or immersion in disinfectant solution.

1. Clean the outside surfaces with a disinfectant solution.

2. Wipe the outside surfaces with a damp cloth and allow to dry before storing or reusing.

PREDICATE LITERATURE

DYONICS

Smith & Nephew Dyonics

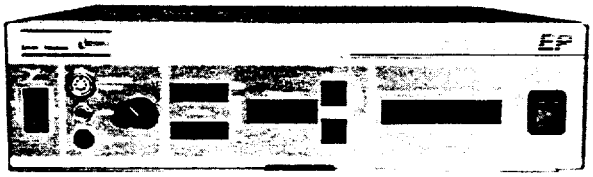
Smith+Nephew
Leadership in Worldwide Orthopaedic Care
160 Dascomb Road, Andover, MA 01810 U.S.A.
Telephone: 508-470-2800 Fax: 508-470-2193
Customer Service: 1-800-343-5717

000031

[redacted]

3500 - PS3500EP Arthroscopic Surgical System	**$10,000**
CONTAINS ONE EACH	
3478	PS3500EP Control Unit, 120V
3476	PS3500EP Motor Drive
3498	Footswitch
4323	Sterilization Tray

3550 - PS3500EP Arthroscopic Surgical System Plus	**$15,000**
CONTAINS ONE EACH	
3478	PS3500EP Control Unit, 120V
3476	PS3500EP Motor Drive
3498	Footswitch
4323	Sterilization Tray
3391	Mini Motor Drive



3478 **$4,200**
PS3500EP Control Unit, 120V

3476 **$5,900**
PS3500EP Motor Drive

For Smith & Nephew Dyonics Customer Service
Please Call 1-800-343-5717

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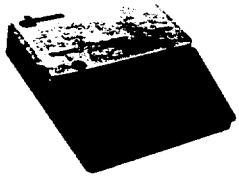
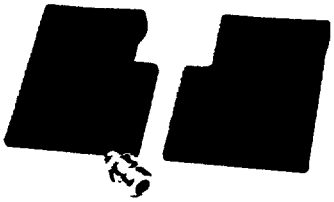
3391 **$5,800**
Mini Motor Drive Unit

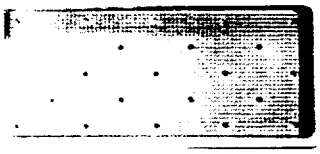


3498 **$485**
Footswitch - New Version with Wider Foot Pedals



4521 **$75**
Footswitch Upgrade Package - Wider Foot Pedals

4323 **$300**
Sterilization Tray



4324 **$150**
Insert for 4323 Tray

[redacted]

3406 - Mini Arthroscopic Surgical System **$9,400**

CONTAINS ONE EACH:

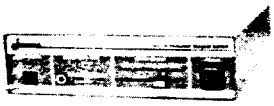
3385	Control Unit
3391	Mini - Motor Drive Unit
4323	Sterilization Tray
1990	Footswitch
3392	Replacement Power Cord

3580 - PS3500EP Mini Arthroscopic Surgical System **$10,000**

CONTAINS ONE EACH:

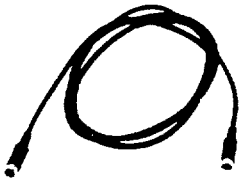
3478	PS3500EP Control Unit
3391	Mini - Motor Drive Unit
4323	Sterilization Tray
3498	Footswitch, Three-Mode, 12-foot Cord
3392	Replacement Power Cord

◆ REPLACEMENT PARTS

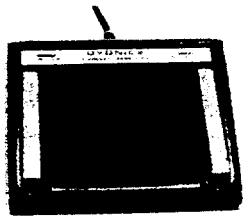


3385 **$3,450**
Mini Control Unit

3391 **$5,800**
Mini Motor Drive Unit



3392 **$430**
Replacement Power Cord



1990 **$470**
Footswitch, Two-mode, 8-ft Cord, for Model 85 and Mini

4323 **$300**
Sterilization Tray

◆ ACCESSORIES

3413 **$125/box**
Small Joint Inflow Set (10 per Box)

3427 - Operative Instrument Set, 2.2mm **$450**

INCLUDES:

CAT. #:	DESCRIPTION:
3214	Cannula, 2.2mm
3216	Obturator, 2.2mm
3215	Trocar, 2.2mm
3312	TMJ/Wrist Probe

3428 **$300**
2.0mm Golden Retriever

3312 **$105**
Wrist Probe

For Smith & Nephew Dyonics Customer Service
Please Call 1-800-343-5717

PREDICATE LITERATURE - PRE-MAY 28, 1976

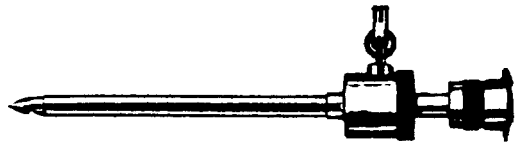
KARL STORZ

Laparoscope

with Enlarged View HOPKINS Telescope 26031 B.

Size: 7 mm. Double Puncture Approach.

26031 G



26031 B

26031 B HOPKINS Forward-Oblique Telescope.
Wide Angle. O. D.: 6.5 mm.
Fiber optic light transmission incorporated.

26031 G Trocar and Cannula with valve and stopcock.
O. D.: 7 mm.

Operating instruments to be used through second trocar **see page** LAP 5–6.

Laparoscope for single puncture approach and documentation with HOPKINS Telescope 26031 B **see page** LAP 8.

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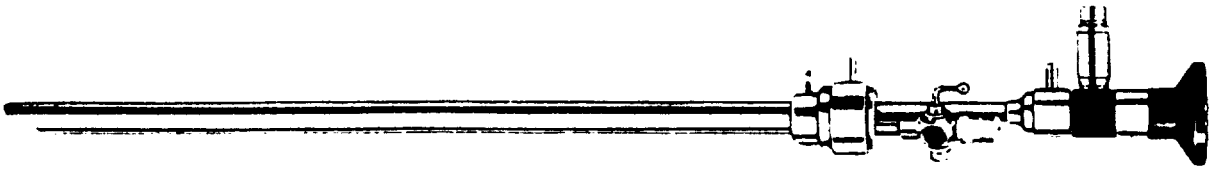
Laparoscope

with Enlarged View HOPKINS Telescope 26031 B.

Size: 11 mm. Single Puncture Approach.

26020 AJ



26031 S 26031 SB 26031 B

WILDHIRT Operating Laparoscope,
consisting of:

26031 B HOPKINS Forward-Oblique Telescope.
Wide Angle. O. D.: 6.5 mm.
Fiber optic light transmission incorporated.

26020 A Trocar and Cannula with valve. O. D.: 11 mm.
Cannula without insulation.

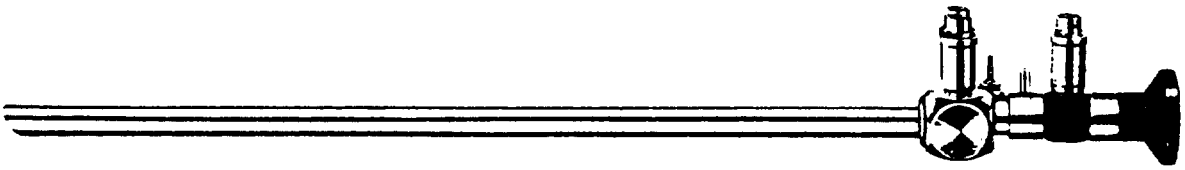
26020 AJ Same. O. D.: 12 mm. With insulated cannula.

26031 S Operating Sheath with stopcock.

26031 SB Telescope Bridge with channel for flexible operating instruments. For use with 26031 S.

Flexible Operating Instruments see page LAP 9.

Accessories for documentation:



26031 CW 26031 B

26031 CW Sheath with built-in fiber optic light transmission.
For use with flash tube 555 A and generator 550 for still photography.

26031 CJ Same. With integral fiber optic light cable.
For photography, cinematography and television.
For use with light sources 558, 493 and 494 A-F.

476.5

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PREDICATE LITERATURE

KARL STORZ

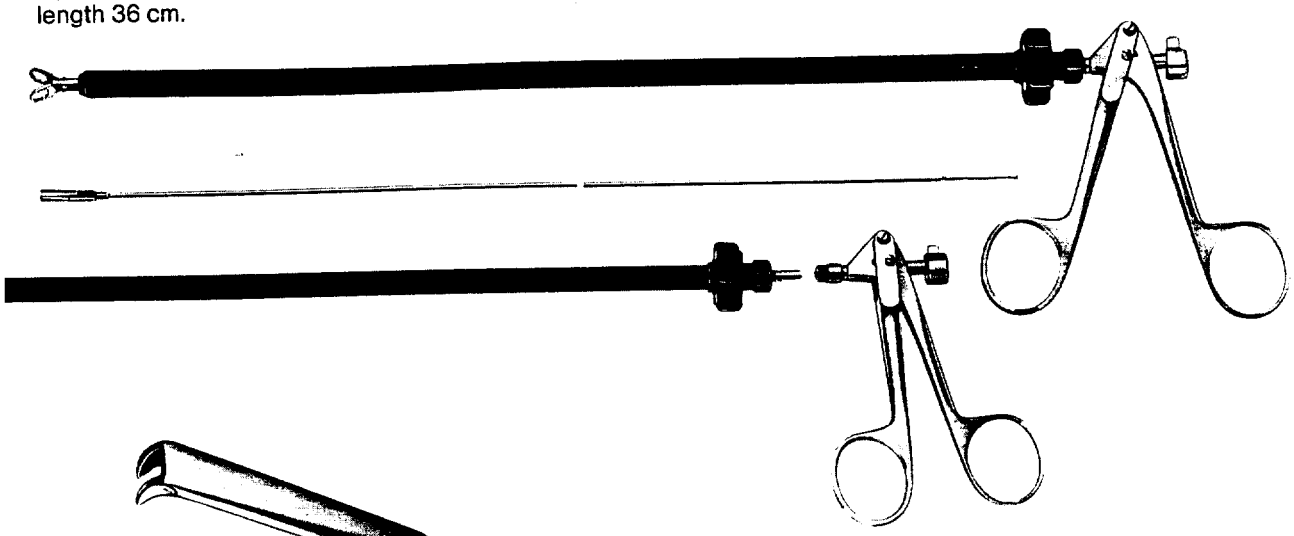
Dissecting and Grasping Forceps

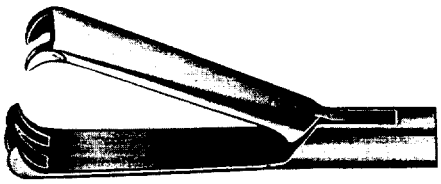
take-apart® – rotating,

without insulation, size 10 mm.

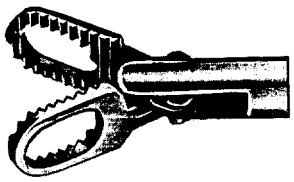
KARL STORZ — ENDOSKOPE

Multiple Puncture Approach.
Operating instruments for use with trocar size 11 mm, length 36 cm.





30422 FS **Take-apart®, rotating Claw Forceps,**
single action jaws,
consisting of:
30552 **Metal Handle,** with ratchet.
30540 **Outer Tube.**
30420 FS **Insert, Claw Forceps.**



30422 TH **Take-apart®, rotating Grasping Forceps,**
double action jaws,
consisting of:
30552 **Metal Handle,** with ratchet.
30540 **Outer Tube.**
30420 TH **Insert Grasping Forceps.**

280080 **Brush for Cleaning,** autoclavable,
package of 5.

3-93

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3

STERILIZATION AND CLEANING

CLEANING AND STERILIZATION INFORMATION FOR KARL STORZ ENDOSCOPIC INSTRUMENTS

I CLEANING

Proper care and maintenance of surgical instruments requires complete disassembly and meticulous mechanical cleaning. Careful attention to detail will prolong the useful life of instruments and protect patients from cross-infection.

(b)(4)

[redacted]

[illegible] BRICATION

All moving parts should be lubricated to prevent "freezing" of stopcocks, forcep jaws and other moving parts. Instruments that have been in contact with dextran may benefit from soaking in an instrument milk bath. A water soluble lubricant can penetrate into moving parts and may help counteract the effects of any residual dextran solution.

Prior to sterilization, some instruments can be partially reassembled. However, tight locking mechanisms (e.g., washer assemblers, trap door valves) and channel caps should not be reassembled, since this might interfere with sterilization.

III. STERILIZATION

In order to achieve the desired standard assurance level (SAL) of 10^{-6}, we recommend steam and EtO sterilization methods. Sterilize as often as needed and/or desired. **Do not sterilize or disinfect the connecting cord in antiseptic solutions**. Discard the device if it is cracked, bent, tarnished or otherwise damaged.

A. Steam Sterilization

(b)(4)

[redacted]

(b)(4)

[redacted]

As per 21 CFR 812.100 (Federal Register, Vol. 43, No. 122, June 23, 1978), maximum acceptable levels of residues following EtO sterilization are as follows (b)(4) [redacted]

(b)(4) [redacted]

4

SCIENTIFIC JOURNAL ARTICLES

ELECTRICAL CUTTING DEVICE FOR LAPAROSCOPIC REMOVAL OF TISSUE FROM THE ABDOMINAL CAVITY

Rolf A. Steiner, MD, Edward Wight, MD, Yona Tadir, MD, and Urs Haller, MD

The extraction of large tissue masses from the abdominal cavity during laparoscopic surgery is a time-consuming, complicated process. A new prototype instrument is introduced that allows quick laparoscopic removal of fibromas, ovaries, or other tissues from the abdomen. A cylinder with a coning knife at its intra-abdominal end is placed inside the trocar sleeve and is rotated by an electrical micro-engine attached to the trocar. Cylindrical tissue blocks are cut step by step out of the main specimen and removed from the peritoneal cavity through the sleeve with a grasping forceps. Tissue removed is suitable for histologic examination. The principal application is morcellation of fibromas, whereas use in ovarian disease is limited. This new device provides a safe and effective approach inside the abdominal cavity. *(Obstet Gynecol 1993;81:471–4)*

From the Departement für Frauenheilkunde, Universitätsspital Zürich, Zürich, Switzerland; and Beckman Laser Institute & Medical Clinic, University of California, Irvine, California.

Construction was supported by J. Anklin AG, Basel, Switzerland, and K. Storz GmbH & Co., Tuttlingen, Germany.

Laparoscopic surgery has become increasingly popular because it offers minimal traumatic effect on the tissue, fewer postoperative complications, shorter convalescence, and better cosmetic results.[1,2] A major problem during laparoscopic operations is removal of large

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1. Vermesh M, Silva PD, Rosen GF, Stein AL, Fossum GT, Sauer MV. Management of unruptured ectopic gestation by linear salpingostomy: A prospective, randomized clinical trial of laparoscopy versus laparotomy. Obstet Gynecol 1989;73:400–4.
2. Nezhat CR, Nezhat FR, Metzger DA, Luciano AA. Adhesion reformation after reproductive surgery by videolaseroscopy. Fertil Steril 1990;53:1008–11.
3. Semm K. Tissue-puncher and loop ligation—new aid for surgical-therapeutic pelviscopy (laparoscopy) endoscopic intraabdominal surgery. Endoscopy 1978;10:119–24.
4. Semm K. Morcellement and suturing using pelviscopy—not a problem any more. Geburtshilfe Frauenheilkd 1991;51:843–6.

Address reprint requests to:
Rolf A. Steiner, MD
Departement für Frauenheilkunde
Universitätsspital Zürich
CH–8091 Zürich
Switzerland

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SUMMARY OF SAFETY AND EFFECTIVENESS

SUMMARY OF SAFETY AND EFFECTIVENESS

The Karl Storz Steiner Electromechanic Morcellator and accessories and the predicate devices are motorized surgical devices which morcellate and remove tissue from the surgical site. These instruments are designed for use by qualified surgeons during gynecological endoscopic procedures.

The device comes into contact with the human body for brief periods of time. The body contact material is commonly used in medical devices for a wide range of applications, and has a long history of biocompatibility for human use.

The Karl Storz Steiner Electromechanic Morcellator and accessories is substantially equivalent to the predicate devices since the basic features, design, and intended uses are the same. The minor differences in design and dimensions between the Karl Storz Steiner Electromechanic Morcellator and accessories and the predicate devices raise no new issues of safety and effectiveness as these design differences have no effect on the performance, function, or intended use of the devices.