K051610

JUL 29 2005

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Hermann Medizintechnik GmbH
Württemberger Str. 26
D-78567 Fridingen Germany

510(k) Summery of Safety and Effectiveness

Titel: Laparoscopes and accessories

April 08, 2005

Submitted by	Ing.-Büro Jung Unterer Winkel 3 D-78573 Wurmlingen
Contact Person	Harald Jung Telefon +49 7461-96 92 36 FAX +49 7461-96 92 37
Trade Name	Laparoscopes and accessories
Common Name	Laparoscopes
Product Code and Classification Name	GCJ, Laparoscope, General & Plastic Surgery
Product Classification	21 CFR § 876.1500

Device Description

The Hans Hermann Laparoscopes and accessories consists of

- various manually operated surgical instruments with and without monopolar high frequency connection
- bipolar electrodes and accessories
- monopolar electrodes and accessories
- several Trocar sleeves and accessories, Verres needles and suction-/irrigation systems,
- several Endoscopes (Laparoscope, Arthroscope, Cystoscope)
- and a light cable

The body contact portions of the Laparoscopes and accessories are composed of surgical grade stainless steel, PTFE, PEEK, several coatings, silicon and brass chromium plated which is commonly used in medical devices for a wide range of applications and have a long history of biocompatibility for human use at short term contact.

Intended Use

The Laparosopes and accessories are intended for use in providing access to and visualization of body cavities, organs, and canals to perform various diagnostic and therapeutic surgical procedures.
The arthroscope is indicated for illumination during joint examinations, arthroscopies, biopsies and diagnosis of joint disease in minimally invasive procedures of the knee, shoulder, wrist (carpal tunnel syndrome), temporal mandibular joint, ankle and elbow.
The bipolar electrodes are use to coagulate and to remove or destroy tissue by the use of bipolar HF current.

Substantial Equivalence

The Laparoscopes and accessories are substantial equivalent to the predicate device of Ackermann, ASAP, Richard Wolf and others, since the basic features, design and intended uses are the same. The minor differences between the Laparoscopes 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.

Performance Data

The devices conform to IEC 60601-2-2 and to the relevant provisions of European Device Directive 93/42/EEC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 2005

Hans Herman GmbH
c/o Mr. Stefan Preiss
TÜV America, Inc.
1775 Old Highway 8
New Brighton, Minnesota 55112

Re: K051610
Trade/Device Name: Laparoscopic Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, GCJ
Dated: July 20, 2005
Received: July 26, 2005

Dear Mr. Preiss:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Laparoscopic instruments

Indications For Use:
The Laparosopes and accessories are intended for use in providing access to and visualization of body cavities, organs, and canals to perform various diagnostic and therapeutic surgical procedures.
The arthroscope is indicated for illumination during joint examinations, arthroscopies, biopsies and diagnosis of joint disease in minimally invasive procedures of the knee, shoulder, wrist (carpal tunnel syndrome), temporal mandibular joint, ankle and elbow.
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Prescription Use yes AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051610

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