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SAFETY & EFFECTIVENESS DATA SUMMARY

Submitters Name, Address & Phone Number:

PAJUNK GmbH
Karl-Hall-Str. 1
D-78187 Geisingen
Germany

Submission Correspondent:

Lyle Howard Corporation
203 Main Street, PMB 166
Flemington, NJ 08822
Attention: Lynette Howard

Classification Name: **Reusable, Monopolar, Surgical Instruments**

Common / Usual Name: **Modular Handle Instruments**

Proprietary Name: **PAJUNK Modular Handled Instruments**

Establishment Registration Number: 9611612

Classification: **Class II, Reg. # 876.1500, GCJ, Laparascope, General & Plastic Surgery**

Performance Standards: **No performance standards have been developed for this device.**

Substantial Equivalence:

The PAJUNK Modular Handle Instruments are substantially equivalent to the Richard Wolf Medical, Modular Forcep and Scissor System, K935270 in design, materials, methods of construction and intended use.

The intended use of the devices to which we claim substantial equivalence:

Modular forceps and scissors system for optional monopolar coagulation which enable a surgeon to grasp, manipulate, dissect, retrieve, biopsy, cut or coagulate internal tissue or organs while performing laparoscopic procedures.

Testing conducted or standards applied to assure safety and effectiveness include but is not limited to:

ISO 11134 – Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization
ISO 11135 – Sterilization of health care products – Requirements for validation and routine control – Ethylene oxide sterilization.
Biological Evaluation of Medical Devices – ISO 10993-1, ISO 10993-5, ISO 10993-12

Description of the new device:

The Pajunk GmbH Modular Handle Instruments are identical in terms of materials, modes of construction, to the Richard Wolf Medical Modular Forcep and Scissor System.

PAJUNK GmbH Modular Handled Instruments consist of three basic parts: Handles, Guidance Tubes and Instrument Inserts.

Three handles constitute the basis of the system. While the free-moving handle opens and closes without locking into place, the handle with ratchet is especially suitable for securing and holding in place. The combination handle incorporates the advantages of these two handles.

The Guidance Tubes have insulated shafts and include diameter of 3mm (Shaft + Insert = One Unit), 5mm and 10mm.

The instrument inserts consist of four basic types: Grasping Forceps, Scissors, Biopsy Punches and Clamps / Needle Holders.

All handles can be combined with all insulated shafts and instrument inserts, regardless of their size and shape.

The shaft screws onto the handle tightly, and it ensures the safe and secure connection of the two elements. Every module of the handle-instrument is kept in place in its bracing fixture, secured against distortion. A snap-on mechanism locks the instrument insert in the shaft (exception: 3mm tube): This whole element can then in turn be latched onto the handle by a special locking device. This latching of the connecting rod and the shaft minimizes the torsion stress exerted upon the instrument insert; the double security against distortion transfers the torque also to the entire shaft.

Jacketed with glass fiber-reinforced plastic, the precise mechanical construction of the PAJUNK handle ensures maximum stability.

Designed for left and right handed use, the ergonomically shaped handles are simple and comfortable to operate. The rotary wheel can be adjusted with a little pressure applied by the index finger. A built-in rotation stop secures the desired position when grasping.

Intended Use:

Instruments insulated for optional monopolar coagulation which enable a surgeon to grasp, manipulate, dissect, retrieve, biopsy, cut or coagulate internal tissue or organs while performing laparoscopic procedures.

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

Safety and Efficacy Information:

The Modular Handled Instruments are well recognized as being safe and effective for the stated intended use. The PAJUNK GmbH Modular Handle Instruments have the same operating principals and intended uses as the competitive modular handle instrument systems already in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 2004

PAJUNK GmbH
c/o Ms. Lynette Howard
Lyle Howard Corporation
203 Main Street, PMB 166
Flemington, New Jersey 08822

Re: K033249
Trade/Device Name: PAJUNK Modular Handle Instruments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: February 18, 2004
Received: February 23, 2004

Dear Ms. Howard:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
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): K033249

Device Name: PAJUNK Modular Handle Instruments

Indications For Use:

Instruments insulated for optional monopolar coagulation which enable a surgeon to grasp, manipulate, dissect, retrieve, biopsy, cut or coagulate internal tissue or organs while performing laparoscopic procedures.

Prescription Use __Yes_____ AND/OR Over-The-Counter Use _No_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Miriam C. Provost
Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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