K011997

JUL 1 0 2001

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Applicant: Pajunk GmbH
Am Holzplatz 5 – 7
D-78187 Geisingen
Germany
Tel. 07704 9291-0

Contact: Martin Hauger
Technical Director

Device Identification:
Common Name:
modular valve handles for adaptable tubes, adaptable suction/irrigation tubes
Trade Name:
modular valve handles for adaptable tubes, adaptable suction/irrigation tubes

Indication and Device Description:

General
The Pajunk modular multifunction suction/irrigation system with pistol handle, maintenance free 2-way valve, many different adaptable tubes and lockable instrument channel for irrigation and aspiration of rinsing liquid in the laparoscopic operating area. The instrument channel automatically opens when instruments are inserted and closes when they are removed. Alternatively the closure of the instrument channel can be opened manually by pressing a pushbutton for example to remove a hook-type instrument or a biopsy. The system can be dismounted/ assembled for cleaning without any tools needed.

Modular valve handles for adaptable tubes
The Pajunk suction/irrigation handles with trumpet valves or maintenance-free 2-way valves for adaptable tubes with connector can be dismounted without any tools. Each handle can be used with any tube having a M8x1 mm connector; i.e. all handles of the series 1298-XX-00 are completely interchangeable.

Adaptable suction/irrigation tubes
The Pajunk adaptable suction/irrigation tubes with connector M8x1 mm can be used with any handle having a M8x1 mm connector. Adaptable suction/irrigation tubes with large LuerLock connector female can be used with any handles of series 1295-XX-00.

Modular multifunction suction/irrigation system with instrument channel
Modular multifunction suction/irrigation system with pistol handle, maintenance-free 2-way valve, many different adaptable tubes and lockable instrument channel Ø 5mm for irrigation and aspiration of rinsing liquid in the laparoscopic operating area. The instrument channel automatically opens when instruments are inserted and closes when they are removed. Alternatively the closure of the instrument channel can be opened manually by pressing a pushbutton for example to remove a hook-type instrument or a biopsy. The system can be dismounted/assembled for cleaning without any tools needed.

Signed:

Mr. Horst Pajunk
General Manager

Mr. Heinrich Pajunk
General Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 0 2001

Pajunk GmbH
c/o Mr. Mark Job
TÜV Product Service
1775 Old Highway 8
New Brighton, Minnesota 55112

Re: K011997
Trade/Device Name: Modular Valve Handles for Adaptable Tubes
Regulation Number: 876.1500
Regulatory Class: II
Product Code: GCJ
Dated: June 13, 2001
Received: June 27, 2001

Dear Mr. Job:

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 (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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

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

PAJUNK

Medizintechnologie

510(k) Number (if known): K011997

Device Name: modular valve handles for adaptable tubes

Indications For Use: suction/irrigation

Systems for irrigation and aspiration of rinsing liquid in the operating area.

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

Concurrence of CDRH, Office of Device Evaluation

for Mark N Melkerson

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

510(k) Number K011997

(Optional Format 3-10-98)