K012771

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PAJUNK

MEDIZINTECHNOLOGIE

NOV 1 4 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:
Trocars, Trocar Sleeves

Trade Name:
Trocar and Trocar Sleeves, Distension System, Anchoring System

Indication and Device Description:

General

The Pajunk Trocars together with the Trocar Sleeves, the Pajunk Balloon Systems and the according accessories are manually operated surgical devices used by physicians for making incisions into the patient's body to allow insertion of endoscopes and endoscopic accessories during general endoscopic and laparoscopic procedures. The devices follow the FDA Draft Guidance for the Content of Premarket Notifications for Endoscopes used in Gastroenterology and Urology, dated 3/17/95.

Trocar Sleeves

The Pajunk Trocar Sleeves are rigid tubes placed with the help of Trocars or Obturators into the patient's body to allow insertion of endoscopes and endoscopic accessories.

Trocars

The trocars are used together with the trocar sleeves for puncture of the patient's body. The trocar is then removed to allow insertion of endoscopes and endoscopic accessories.

Safety –Trocars

The Pajunk Safety-Trocar features a sharp, beveled tip that is covered by an inside, spring loaded, blunt obturator (Veress-concept). During puncture, the obturator is pushed into the shaft against the force of the spring and thus releases the cutting tip which can now penetrate the skin layers. As soon as the abdominal space is reached, the blunt obturator is moved forward by the spring, covers the cutting tip and prevents injuries in the abdomen.

Distension System

The PAJUNK distension balloon system is indicated for laparoscopic procedures specially in extraperitoneal surgery, where dissection of tissue in the extraperitoneal space under direct view is essential. Contraindications: The distention balloon system should not be used in cases where previous operations in the extraperitoneal space caused adhesions in the area of the extraperitoneal organs.

Structural Balloon System

The PAJUNK structural balloon system is indicated for laparoscopic procedures specially in extraperitoneal surgery, where a solid anchored and gas-tight entry port with an instrument

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channel together with a mechanical support of the extraperitoneal work space is needed. The inflation of the balloon causes a continuing dissection and anchoring in the extraperitoneal work space. Contraindications: The structural balloon system should not be used in cases where previous operations in the extraperitoneal space caused adhesions in the area of the extraperitoneal organs.

Ring-Anchor Balloon System
The PAJUNK Ring-Anchor balloon system is indicated for laparoscopic procedures specially in extraperitoneal surgery, where a solid anchored and gas-tight entry port with an instrument channel is needed. Contraindications: The Ring-Anchor balloon system should not be used in cases where previous operations in the extraperitoneal space caused adhesions in the area of the extraperitoneal organs.

Accessories:

Disposable Valve Top
The disposable valve top is used with the Pajunk trocar sleeves and provides the same intended use. The valve is used instead of the trap door valve. The top is made out of polymer instead out of chromated brass. The metal tube is reusable and identical to the ones of the Pajunk trocar sleeves. The advantage is the easier cleaning, sterilization and assembling procedure.

Fixable Slide Cones
The Pajunk fixable slide cones with or without a fixation thread and with suture holders on both sides have been designed for first puncture technique according to Hasson in laparoscopic applications.

Reducer Sleeve
The reducer sleeve is inserted into the actually used trocar sleeve to reduce the diameter for improved guide and gas-tight insertion of endoscopic surgical instruments with outer diameters smaller than the nominal inner diameter of the trocar sleeve.

Dilation Set
If the actually applied trocar sleeve does not provide sufficient space for needed endoscopes and endoscopic accessories or endoscopic surgical instrument it can be replaced with a larger trocar sleeve.

Trocar Stop
The trocar stop with fixation thread is used to fixate the insertion of the trocar sleeve. The trocar sleeve is fixed by hand with a screw.

Substantial Equivalence:
The Pajunk Trocar and Trocar Sleeves, Distension System, the Anchoring System and accessories are substantially equivalent to the predicate devices since the basic features and intended uses are similar. The minor differences between the Pajunk Trocar and Trocar Sleeves, Distension System, the Anchoring System and accessories and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed:

Martin Hauger
Technical Director

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pajunk GmbH
c/o Mr. Mark Job
510(k) Program Manager
TŰV Product Service, Inc.
1775 Old Highway 8
New Brighton, Minnesota 55112

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Re: K012771
Trade/Device Name: Trocars, Trocar Sleeves, Model 1287; Distension System, Ring-Anchor Balloon System
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: October 1, 2001
Received: October 3, 2001

Dear Mr. Job:

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 and additionally 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

K012771

NOV 1 4 2001

510(k) Number (if known): K012771

Device Name: Trocar Sleeves

Indications For Use:

Manually operated surgical device intended for making incisions into the patient's body to allow insertion of endoscopes and endoscopic accessories during general endoscopic and laparoscopic procedures

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N Milhern

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

510(k) Number K012771

510(k) Number (if known): K012771

Device Name: Trocars

Indications For Use:

Manually operated surgical device intended for making incisions into the patient's body to allow insertion of endoscopes and endoscopic accessories during general endoscopic and laparoscopic procedures

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N. Milhoan

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

510(k) Number K012771

510(k) Number (if known): K012771

Device Name: Distension System

Indications For Use:

Manually operated surgical device intended for creating a surgical space by dissecting layers of connective tissue along natural planes to allow insertion of endoscopes and endoscopic accessories during general endoscopic and laparoscopic procedures

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N Milhern

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

510(k) Number K012771

510(k) Number (if known): K012771

Device Name: Ring-Anchor Balloon System

Indications For Use:

Manually operated surgical device intended for providing a well anchored and tight instrument channel to allow insertion of endoscopes and endoscopic accessories during general endoscopic and laparoscopic procedures

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N. Milhauser

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

510(k) Number K012771