

K063528

**Premarket Notification Submission**  
**TrocaSys**



**510(k) Premarket Notification Submission:**

**Summary of Safety and Effectiveness**

**Date of Preparation: November 6<sup>th</sup> 2006**

**JAN 17 2007**

**Submitter Information/ production site:**

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**Contact:**

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**Establishment Registration Number:**

9611612

**Device Information:**

Device Name: **Disposable Trocar System**  
Trade Names: **TrocaSys**  
Common Name: **Laparoscope, General and Plastic surgery**  
Classification Name: **Endoscope and accessories**  
Classification Reference: **21 CFR §876.1500, April 1, 2005**  
Establishment Registration Number: **9611612**  
Classification: **Regulatory Class: II**  
Product Code: **GCJ**  
Panel: **General & Plastic Surgery**  
Predicate Devices: **K012771: Pajunks reusable Trocars, trocar sleeves, dilation balloons and trocar Systems**

### Device Description:

The Pajunk TrocaSys consists of disposable trocar sleeves, disposable trocars and obturators and disposable valves (i.e. TrocaTec, TrocaPort, Hasson system for example for insufflation). The system is based on Pajunks reusable Trocars, Trocar sleeves and Accessories already cleared in K012771. The technical description remains unchanged.

The systems and its 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The devices follow the FDA Draft Guidance for the Content of Premarket Notifications for Endoscopes used in Gastroenterology and Urology, dated 3/17/95.

The trocars and obturators are used together with the trocar sleeves for puncture of the patient's body. After having made the incision, the trocar is removed to allow insertion of endoscopes and endoscopic accessories.

The Disposable Hasson Cone, Disposable obturators/ trocars, Disposable Trocar valve, Disposable TrocaTec and Disposable TrocaPort are available seperately.

For a detailed device description please refer to section 11.0 of this submission.

### Disposable TrocaPort

The Pajunk TrocaSys is a manually operated surgical device intended for making incisions into the patient's body to allow the insertion of endoscopes and endoscopic accessories during general endoscopic and laparoscopic procedures. The TrocaPort is a component of the system available seperately.

### Disposable TrocaTec

The Pajunk TrocaSys is a manually operated surgical device intended for making incisions into the patient's body to allow the insertion of endoscopes and endoscopic accessories during general endoscopic and laparoscopic procedures. The TrocaTec is a component of the system available seperately.

### Disposable Trocar valve

The Pajunk TrocaSys is a manually operated surgical device intended for making incisions into the patient's body to allow the insertion of endoscopes and endoscopic accessories during general endoscopic and laparoscopic procedures. The disposable Trocar valve is a component of the system available seperately. It may be used with Pajunks dilation balloon systems also.

### Disposable obturators/ trocars

The Pajunk TrocaSys is a manually operated surgical device intended for making incisions into the patient's body to allow the insertion of endoscopes and endoscopic accessories during general endoscopic and laparoscopic procedures. The obturators and trocars are components of the system available seperately. They may be used with Pajunks dilation balloon systems also.

### Disposable Hasson Cone

The Pajunk TrocaSys is a manually operated surgical device intended for making incisions into the patient's body to allow the insertion of endoscopes and endoscopic accessories during general endoscopic and laparoscopic procedures. The Hasson Cone is a component of the system available seperately.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Pajunk GmbH Medizintechnologie  
% Christian Quass  
Regulatory Affairs  
Karl-Hall-Strasse 01  
78187 Geisingen, Germany

JAN 17 2007

Re: K063528

Trade/Device Name: TrocaSys disposable Trocar System  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: GCJ  
Dated: January 4, 2007  
Received: January 8, 2006

Dear Christian Quass:

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.

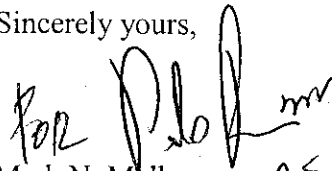
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Christian Quass

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Handwritten signature of Mark N. Melkerson, including initials 'mm' and 'DGP'.

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

Enclosure

Premarket Notification Submission

TrocaSys



Indications for use

510(k) Number:

Device Name: TrocaSys disposable Trocar System

Indications for Use:

The Pajunk TrocaSys is a manually operated surgical device intended for making incisions into the patient's body to allow the insertion of endoscopes and endoscopic accessories during general endoscopic and laparoscopic procedures.

Prescription Use   X    
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(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   K063528