

K090631

PAJUNK®'s Balloons and Balloon Systems
510(k) Premarket Notification Submission



510(k) Premarket Notification Submission:

Summary of Safety and Effectiveness

APR 16 2009

Date of Preparation: December 10th 2008

Submitter Information/ production site:

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Establishment Registration Number: **9611612**

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Contact

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Device Information:

Contract Sterilizer:

External service provider located in Europe

Device Name: **PAJUNK®'s Balloons and Balloon systems**
Trade Names: **PAJUNK®'s Balloons and Balloon systems**
Common Name: **Balloon Systems for fixation, distension and dilation**
Classification Name: **laparoscope, general & plastic surgery**
Classification Reference: **21 CFR §876.1500, April 1, 2008**
Establishment Registration Number: **9611612**
Regulatory Class: **II**
Product Code: **GCJ**
Panel: **General & Plastic Surgery**
Predicate Devices:

- K935426** Preperitoneal Distention Balloon System
- K973046** Spacemaker surgical Balloon dissector, Spacemaker
- K042412** Modified Spacemaker system

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Device Description:

The PAJUNK® Balloon Systems for dilation facilitate safe and effective dissection of the preperitoneal space under direct view. Orientation during minimal invasive procedures is made easier. Three different shaped balloons are available for either unilateral or bilateral purposes.

The structural balloon is particularly suitable for preperitoneal access. The design of the balloon simplifies the separation of the peritoneum from the abdominal wall. Additionally it prevents the peritoneal space from collapsing in the case of a loss of gas.

The ring-anchor balloon is also suitable for gastight accessing of the preperitoneal space. The seal is made by inflating the ring-anchor balloon and then advancing and securing the fastening device. Insufflation is performed via the built-in stop cock.

Predicate Devices:

This 510(k) is submitted in order to clarify content of former PMN (K012771) and at the same time add slightly modified variants. The basic design has been cleared by FDA in K012771.

Predicate devices with identical indications of use are:

1. **K935426** Preperitoneal Distention Balloon System
2. **K973046** Spacemaker surgical Balloon dissector, Spacemaker
3. **K042412** Modified Spacemaker system

The detailed discussion of substantial equivalence can be found in Section 12 of this submission.

The syringe (30ml) and the ball pump are class I accessories exempt from PMN-process.

Sterilization

The disposable parts are single use, sterilized with EtO. The contract sterilizer and the sterilizing process is the same as that used for all PAJUNK GmbH Medizintechnologie's Products already cleared for market.

The **reusable valves and reusable obturators** are supplied non-sterile. It is cleared in 510(k) K012771.

Technology Characteristics:

The components are listed in a table in section 11 of this submission.

Conclusion:

The comparison of the predicate devices and the subject device in section 12 of this submission as well as the validated sterilization process and the results of the bench testing and bench marking demonstrates that the proposed devices are substantially equivalent to the predicate devices and identical in technical description to devices already cleared for market and therefore demonstrated to be safe and effective. Based on the clinical evaluation, the biocompatibility testing and the bench testing conducted, safety and effectiveness as well as efficacy of PAJUNK®'s **balloons and balloon systems for dilation and fixation** is proven.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pajunk GmbH Medizintechnologie
% Ms. Patricia Weisbrod
Regulatory Affairs
Karl-Hall-Strasse 01
78187 Geisingen
Germany

APR 16 2009

Re: K090631

Trade/Device Name: Balloon systems
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 8, 2009
Received: April 6, 2009

Dear Ms. Weisbrod:

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.

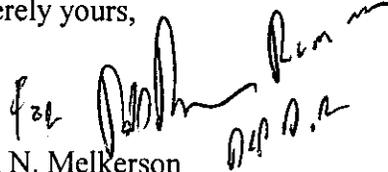
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 - Ms. Patricia Weisbrod

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". To the right of the signature, there is a date "11/10/02".

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

Enclosure

PAJUNK®'s Balloons and Balloon Systems
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Indications for use

510(k) Number:

Device Name: **Balloon systems**

Indications for Use:

The PAJUNK **Balloon systems** are indicated for patients undergoing laparoscopic surgical procedures requiring a sealed port of access and / or tissue retraction. This is also indicated in patients undergoing laparoscopic surgery requiring a sealed port of access and / or tissue separation in extraperitoneal procedures, such as in hernia repair.

The PAJUNK **Obturator** is intended for use in establishing a port of access for insertion of endoscopic instruments into the abdominal cavity or extraperitoneal space in abdominal and extraperitoneal surgery.

Prescription Use **X**

AND/OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(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)

Neil R. Oden, Esq.

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number **K090631**