

K040965

Section 6.0

SEP - 7 2004

510(k) Summary of Safety and Effectiveness

This section contains the 510(k) Summary of Safety and Effectiveness.
(This document can be copied and submitted to interested parties as required by 21CFR 807.92).

510(k) Summary of Safety and Effectiveness

Submitter's Information:

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USA Contact:

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Device Name:

Trade Names: Tuohy needle; Quincke needle; Chiba needle; Crawford needle
Common Names: Anesthesia conduction needles, epidural/spinal needles

Classification Name: Anesthesia conduction needles
(Reference, 21 CFR, 868.5150, April 1 2003)

Product Class: Class II

Product Code: BSP, MIA

Preparation date of summary: March 2, 2004

Predicate Devices:

1. Becton Dickinson spinal needles: K953790 & K954953.
2. Pajunk's anesthesia conduction needles - Tuohy, Quincke, Chiba, and Crawford – consist of the same plastic luer hub and metal cannula materials as Pajunk's Sprotte needles cleared under 510(k) numbers K911202, K911221, K911260, and K923003. The only difference between these needle types is the needle tip, which is either pencil-point-tip (Sprotte), bent and sharp needle tip (Tuohy), sharp needle tip (Quincke), elongated sharp needle tip (Chiba), or short needle tip (Crawford).

Device Description:

Anesthesia conduction needles consist of a luer hub, a stainless steel cannula with various tip types, and a stainless steel stylet. These needles are provided as sterile, single use, disposable devices. They may be packaged individually or included in regional anesthesia trays (kits). Anesthesia conduction needles fit into an introducer needle. This is a simple hypodermic needle to make the initial puncture through the skin to aid in the placement of the anesthesia conduction needle. The later can facilitate the placement of an epidural catheter for continuous infusion of local anesthetics into the epidural space for longer pain relief.

The Pajunk anesthesia conduction needles - Tuohy, Quincke, Chiba, and Crawford – are single use, sterile, non-pyrogenic and latex-free medical devices for transient delivery of anesthetics during regional anesthesia. The cannula is stabilized during puncture with use of an inner stylet (mandrin). This stylet is withdrawn after the anesthesia conduction needle has reached its anatomical site for regional anesthesia. Then the anesthetics can be applied transiently (i.e. within minutes) by the professional anesthetist. Alternatively or additionally, an epidural catheter may be placed through the anesthesia conduction needle. The needle is withdrawn and the epidural catheter tip may remain in the epidural space for pain treatment.

Intended Use:

Pajunk's anesthesia conduction needles - Tuohy, Quincke, Chiba, and Crawford - are intended for the transient delivery of anesthetics to provide regional anesthesia or to facilitate placement of an epidural catheter.

Technology Characteristics:

The Pajunk anesthesia conduction needles - Tuohy, Quincke, Chiba, and Crawford – have the same technological characteristics as the predicate devices identified above.

The Pajunk anesthesia conduction needles - Tuohy, Quincke, Chiba, and Crawford – are equivalent in design, physical dimensions, luer hub, metal and plastics materials, and packaging to Pajunk's Sprotte needles cleared under 510(k) numbers K911202, K911221, K911260, and K923003.

Biocompatibility testing of Pajunk's anesthesia conduction needles is located in Section 7 of this submission.

Conclusion:

The majority of anesthesia conduction needles are pre-amendment devices. This is due to the fact that anesthesia conduction needles have been available to anesthesiologists for about 100 years. The comparison between the predicate devices and the proposed devices demonstrates that the proposed devices are safe and effective, as well as substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 7 2004

Pajunk GMBH
C/O Ms. Lynette L. Howard
Submission Corespondent
Lyle Howard Corporation
203 Main Street, PMB 166
Flemington, New Jersey 08822

Re: K040965
Trade/Device Name: Pajunk Anesthesia Conduction Needles
Regulation Number: 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: August 16, 2004
Received: August 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) 594-4646. 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,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use - Revised

510(k) Number (if known):

Device Name: Pajunk Anesthesia Conduction Needles

Indications For Use:

Pajunk's anesthesia conduction needles - Tuohy, Quincke, Chiba, and Crawford - are intended for the transient delivery of anesthetics to provide regional anesthesia or to facilitate placement of an epidural catheter.

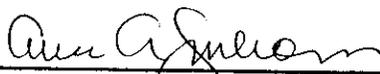
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

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