JUL 11 2002

K013892

June 27, 2002 Reply to William Noe and Angela Smith, FDA

BALLARD
MEDICAL PRODUCTS

Appendix F
Attachment 1.0
Revised Summary Statement

510(k) Premarket Notification
Summary Statement

June 27, 2002

Submitter information per 807.92(a)(1):
Sydnee F. McMillan, RN, BSN Senior Regulatory Affairs Specialist
Ballard Medical Products, a wholly owned subsidiary of the Kimberly Clark Corporation
12050 Lone Peak Parkway
Draper, UT 84020
Tel. (801) 523-5295
Fax (801) 572-6869

Proprietary Name per 807.92(a)(2):
Ballard Medical Products Lutz Needle

Common name per 807.92(a)(2):
Anesthetic conduction needles

Classification per 807.92(a)(2):
Class II through the Anesthesiology Panel per 21 CFR 868.5150.
Classification name: Needle, Conduction, Anesthetic (with or without introducer).
Product code: BSP

Legally marketed equivalent(s) per 807.92(a)(3):
B. Braun Epidural Needle #K923400
Ballard Tuohy Needle #K000495.

Device Description:
The needle presented in this application is equivalent to other anesthesia conduction needles on the market that have been approved for marketing through the Premarket notification process. This is a "me too" device. The subject device has the same technological characteristics as legally marketed predicate devices. The features, specifications, materials, and mode of action are substantially equivalent.

Intended use per 807.92(a)(5):
The intended use of the **Lutz Needle** is for the administration of single-shot epidural anesthesia.

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Technological Characteristics (equivalence to predicate devices) per 807.92(a)(6):
The general design characteristics and function is similar in that it meets performance standards where applicable for:

Stainless steel components: ISO 9626
Hub: ISO 594
Hub-to needle bond strength: ISO 7864

Determination of substantial equivalence (non-clinical data) per 807.92(b)(1):

The **Lutz Needle** was tested (in vitro) as follows: First article inspection for dimensional criteria and conformance to standards.

Conclusions from non-clinical data per 807.92(b)(3):

Based on the indications for use, technological characteristics and performance testing, use of the **Lutz Needle** for its intended use is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2002

Ms. Sydnee F. McMillan, RN, BSN
Senior Regulatory Affairs Specialist
Ballard Medical Products
12050 S. Lone Peak Parkway
Draper, Utah 84020

Re: K013892
Trade Name: Lutz Needle
Regulation Number: 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: May 6, 2002
Received: May 8, 2002

Dear Ms. McMillan:

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) 594-4646. 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

July 9, 2002 Reply to Joanna Weitershasen, FDA

Appendix F
Attachment 1.0
Device Indication for Use Statement

510(k) Number: K013892

Device Name: Lutz Needle

Indication For Use:

To introduce single-shot anesthetic agents into the epidural space.

DO NOT WRITE BELOW THIS LINE. CONTINUE ON A SECOND PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☑ OR Over-The-Counter Use ☐

K013892

(Division Sign-Off)
Division of ~~Cardiovascular, Respiratory, and Neurological Devices~~ Anesthesia, General Hospital, Infection Control & Dental Device
510(k) Number K013892