Appendix F
Attachment 3.0

K030721 1/3

February 28, 2003

MAR 31 2003

510(k) Premarket Notification Summary per 807.92(a)

Submitter Information: Cindy Ellis
Ballard Medical Products
12050 Lone Peak Parkway
Draper, UT 84020
Tel. 801-572-6800 extension 2452
Fax 801-572-6869

Common/Usual Name: Paracentesis Kit, Tray and Needle

Trade Name: Quick-Tap® Paracentesis Kit, Tray and Needle

Classification Name: Kit, Surgical – General
General and Plastic Surgery
21 CFR 878
79 LRO
Class II

Predicate Device: Paracentesis Tray
K950574

Paracentesis Kit
K961863

Device Description:

Abdominal paracentesis is a procedure used to remove bodily fluid from the peritoneal cavity. Fluid can be the result of liver disease, congestive heart failure or other disease that result in "ascites" fluid. Fluid may also be in the form of blood from perforated organs due to trauma. The fluid is susceptible to infection.
Abdominal paracentesis provides therapeutic relief to patients who experience bloating and difficult breathing. The procedure serves a diagnostic purpose, as well. Typically, fluid specimens are sent to a laboratory for microbiological, chemical and histological analysis.
Abdominal paracentesis can be performed at bedside or in a treatment center. The patient is prepped using sterile technique and local anesthetic. The sitting position is preferred so that gravity can assist. If preferred, a skin nick is performed with a scalpel and a large bore outer cannula is introduced into the peritoneal cavity midline between the umbilicus and pubis. A syringe can be used to collect the first sample of fluid from the patient confirming a suitable puncture site. The inner needle is withdrawn and disposed of leaving the outer cannula in place. Specimen tubes stand ready for specimen collection. The large majority of fluid is drained or suctioned into bags or large containers and disposed of. There are no guidelines or standard of care that define the amount or rate of

ascites fluid evacuation other than to monitor for signs of hypovolemic shock. One to two liters can be evacuated at one session. After paracentesis the cannula is removed and an adhesive bandage is placed over the puncture site. The patient is then monitored briefly for signs of distress such as persistent bleeding from the puncture site, faintness, anxiety, abnormal pulse, temperature etc.

Complications are rare but can include hemorrhage, perforation of abdominal organs, wound infection and hypovolemic shock.

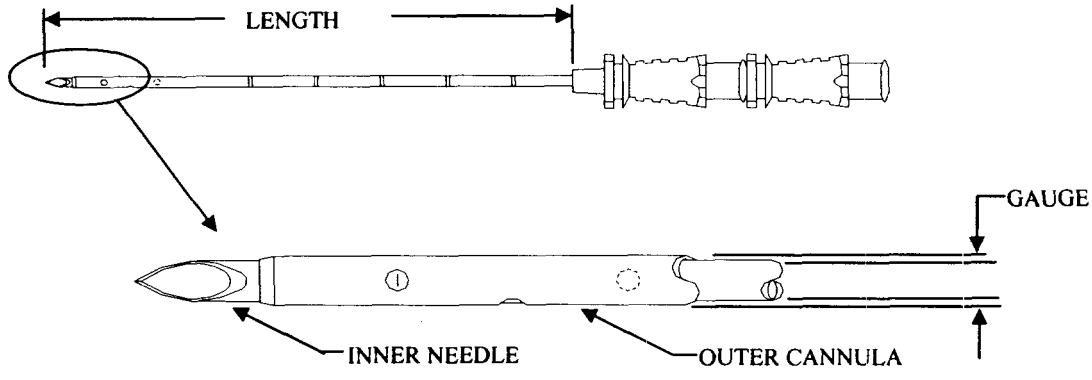

Figure A-1: Caldwell® Paracentesis Needle

The Caldwell® Paracentesis Needle/Cannula

There are a variety of disposable instruments used for paracentesis. These include generic angio-introducer catheters and specific needle/cannula combinations for paracentesis. Figure A-I illustrates the Ballard, Caldwell® Paracentesis Needle/Cannula.

Our proposed paracentesis needles (and thus trays and kits) are substantially equivalent in design, composition, technology and function to our present paracentesis trays (see predicate devices).

Intended Use:
Intended to drain fluid from the abdominal cavity (Paracentesis procedure).

Technological Characteristics (equivalence to predicate device) per 807.92(a)(6):

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Characteristic	Subject Device This submission	Predicate Device K950574	Predicate Device K961863
Needle length	2.25" 3.25" 4.75"	3.25"	3.25"
Gradient Markings	Etched gradient markings	NA	NA
Needle diameter	15 gauge 18 gauge	17 gauge	15 gauge 17 gauge

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Determination of Substantial Equivalence (non-clinical data) per 807.92(b)(1):

The following tests were performed on the Quick-Tap® Paracentesis Needles.

1. **Tensile tests**
2. **Flow rate**
3. **Visual**

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

Based on the indications for use, technological characteristics, and performance testing, the Ballard Quick-Tap® Paracentesis Kit, Tray and Needles are safe and effective for the intended use described above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2003

Ms. Cindy Ellis
Regulatory Affairs Specialist
Ballard Medical Products
12050 Lone Peak Parkway
Draper, Utah 84020

Re: K030721
Trade/Device Name: Quick-Tap® Paracentesis Tray, Kit and Needle
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical drape and drape accessories
Regulatory Class: II
Product Code: LRO
Dated: February 28, 2003
Received: March 7, 2003

Dear Ms. Ellis:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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 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.

In addition, we have determined that your device kit contains lidocaine which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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, please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for 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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): unknown K030721

Device Name: Quick-Tap® Paracentesis Tray, Kit and Needle

Indications for Use: The Quick-Tap® Paracentesis Kit, Tray and Needle are indicated to relieve pressure by draining fluid from the peritoneal space. The fluid may be undergo diagnostic testing to assess for chemistries, infection or abnormal cells.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

PRESCRIPTION USE X **OR OVER-THE-COUNTER USE**____

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030721

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