K022398

BALLARD
MEDICAL PRODUCTS

Appendix F
Attachment 3.0

OCT 11 2002

July 19, 2002

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
Fax 801-572-6869

Common/Usual Name: Biopsy Forceps, Non-Electric, Reusable, Non-Ridged for use with bronchoscopes

Trade Name: NA

Classification Name: Forceps, Biopsy, Bronchoscope (Non-Rigid)
Ear Nose and Throat
21 CFR 874.4680
77BWH

Predicate Device: Olympus FB Series Biopsy Forcep
510(k) K962555

Device Description:

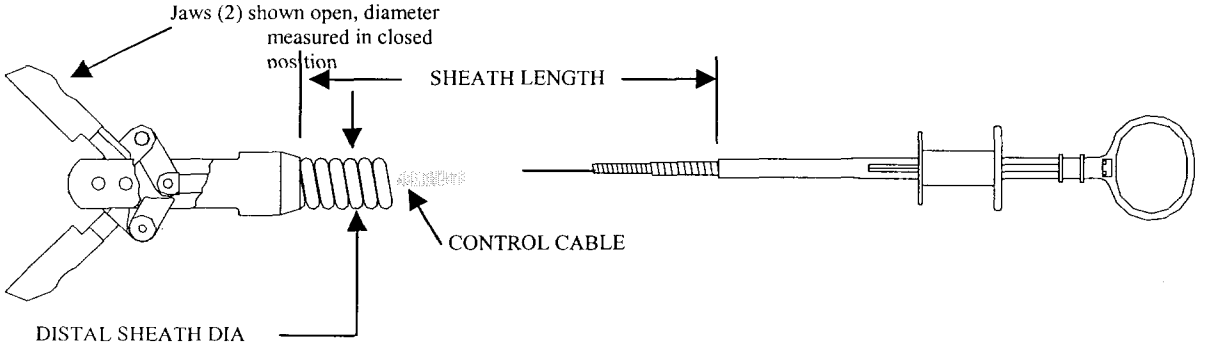

Figure A-1: Bronchial Forceps w/ exploded, breakaway detail of distal end

Figure A-1 depicts all but a few reusable biopsy forceps designs. All operate on a 4-bar linkage arrangement as shown. Transverse motion of the control cable results in the pendulum motion of the jaw pair. The handle consists of a slide, finger spool or finger ring arrangement and a thumb ring. The jaws are actuated by transverse motion of the finger spool that connects to the control cable. The control cable is connected to the clevis. The

linkages are hinged on small pins, the jaws rotate about an axle pin that is supported by the fork. With the exception of the handle, all the components are fabricated from ASTM 302, 303 or 304 stainless steel. The handle components are fabricated from a suitable material able to withstand several reprocessing cycles. The physical characteristics of this device as well as 510(k) predicate devices are described below.

Intended Use: Intended to remove, by cutting, a specimen of tissue for microscopic examination from the lungs or bronchial passageways.
Patient population; Any patient demonstrating an abnormality or condition indicative of malignancy or benign obstruction as noted through bronchoscopy, x-ray, MRI, etc.

Technological Characteristics (equivalence to predicate device) per 807.92(a)(6):
The general design characteristics and function of the Ballard device is similar to the Olympus device.

Characteristic	Subject Device This submission	Predicate Device (Olympus)
Typical label/advertising descriptors		
Sheath length	120cm	105cm
Sheath diameter	1.6mm	1.6mm
Jaw diameter	1.8mm	1.8mm
Jaw geometry	Ellipsoid, fenestrated, no spike	Ellipsoid, fenestrated, no spike plus various others
Recommended Reprocessing		
Soak	Immediately after use	Immediately after use 5min to 3 hrs.
Enzymatic wash	Thoroughly clean with soft brush to remove particulate. Dry with sponge or gauze	N/A
Ultrasonic cleaning	40KHz, 10 minutes	30 minutes
Rinse	Clean running tap water	Clean running tap water
Autoclave	Pre-vacuum cycle 134°C 4min. exposure time .2Mpa pressure Gravity cycle 134°C 15 minute exposure time .310Mpa pressure	Pre-vacuum 132°C-134°C 5min. exposure time

Determination of Substantial Equivalence (non-clinical data) per 807.92(b)(1):
The following tests were performed on the Ballard Reusable Bronchial Biopsy Forceps.

1. **Functional**
2. **Sterilization**
3. **Reprocessing**
4. **Tensile**

Conclusions from non-clinical data per 807.92(b)(3):
Based on the indications for use, technological characteristics, and performance testing, the Ballard Reusable Bronchial Biopsy Forceps is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

Ballard Medical Products
c/o Cindy Ellis
Regulatory Affairs Specialist
12050 Lone Peak Parkway
Draper, UT 84020

Re: K022398
Trade/Device Name: Reusable Bronchial Biopsy Forceps
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories.
Regulatory Class: Class II
Product Code: BWH
Dated: July 19, 2002
Received: July 23, 2002

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 (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) 594-4613. 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,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

BALLARD
MEDICAL PRODUCTS

APPENDIX A
ATTACHMENT 2.0
INTENDED USE STATEMENT

Reusable Bronchial Biopsy Forceps

INTENDED USE STATEMENT

Intended to remove, by cutting, a specimen of tissue for microscopic examination from the lungs.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

10/11/02

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K022396

A subsidiary of
Kimberly-Clark Corporation

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