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BALLARD®
Medical Products

12050 Lone Peak Parkway
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(801) 572-6800
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Appendix F
Attachment 1.0
Summary Statement

510(k) Premarket Notification Summary Statement

Ballard Medical Products® Faciletome™ Bow String Papillotome

Friday, February 05, 1999

Submitter Information per 807.92(a)(1):

E. Martin Chamberlain
Ballard Medical Products
12050 Lone Peak Parkway
Draper, UT., 84020
Tel. (801) 572 - 6800
Fax. (801) 572 - 6869

Proprietary Name per 807.92(a)(2):

The Ballard Medical Products® Faciletome™ Bow String Papillotome

Common Name per 807.92(a)(2):

Biliary Bow String Papillotome or Sphincterotome

Classification per 807.92(a)(2):

The Ballard Medical Products® Faciletome™ Bow String Papillotome has been classified a Class II device through the Gastrointestinal - Urology Panel per 21 CFR Part 876.4300. Classification name is: Unit, Electrosurgical, Endoscopic (With or Without Accessories). Product Code 78KNS.

Legally marketed equivalent(s) per 807.92(a)(3):

The Ballard Medical Products® Faciletome™ Bow String Papillotome device is substantially equivalent to the Wiltek Medical, Inc. papillotomes; the subject of 510(k) #K894861, marketed under the trade names of Accuratome³™, Accuratome™, and Double Lumen™ Papillotome.

Description of the device 807.92(a)(4):

The bow string papillotome is one of the most commonly used E.R.C.P. (Endoscopic Retrograde Colangio-Pancreatography) devices and has been established in the industry for several years. It has evolved into several variations on one general theme, facilitating entrance into the biliary tree. It performs this by housing a stainless steel mono-filament or stranded wire that is to be the active wire when monopolar, surgical power is introduced into the device handle connection. A sheath runs the length of the wire and allows only that portion of the wire that is needed to cut be exposed and insulates the remainder from the patient. The bow geometry and wire tension aid in cutting the tissue at the precise location. The wire is attached to a handle, that when manipulated, allows the operator to apply tension forming a "bow" at the distal end.

The Ballard Medical Products® Faciletome™ Bow String Papillotome is placed under direct vision of a duodenscope, with or without fluoroscopic aid. The single lumen, double lumen and triple lumen designs have a variety of cutting wire lengths as well as a variety of precurved tip configurations in the precurved model type.

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Intended Use per 807.92(a)(5):

The Ballard Medical Products® Faciletome™ Bow String Papillotome(s) is intended to be used for patients requiring transendoscopic cannulation and sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi.

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

The Ballard Medical Products® Faciletome™ Bow String Papillotome(s) are substantially equivalent to the Wiltek Medical, Inc. papillotomes; K894861, marketed under the trade names of Accuratome³™, Accuratome™, and Double Lumen™ Papillotome.

The general design characteristics and functionality are similar in that they are all one piece construction which include: single or multiple lumen shafts, a one piece handle system, multiple cutting wire lengths and construction with precurved tips in multiple lengths.

The above devices may be advanced with or without employing a 0.035 inch guidewire through the biopsy channel of a duodenoscope with optional use of fluoroscopy.

In all the devices, current is applied through the cutting wire to incise the Papilla of Vater or Sphincter of Oddi. A Touhy Borst may be attached to the guidewire lumens of the multiple lumen devices to assist in placement, and minimize contrast leakage.

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

The following in vitro tests were performed on the proposed Ballard Medical Products® Faciletome™ Bow String Papillotome:

- A) High Frequency Leakage Current
- B) Capacitive Coupling between device active wire and recommended guidewire(s).
- C) Verification of Frequency and Voltage Signal (800V p-p @ 1MHz)
- D) Dielectric Withstand Test

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

Based on the indications for use, technological characteristics, and performance testing, the Ballard Medical Products® Faciletome™ Bow String Papillotome has been shown to be safe and effective for its intended use.



MAY 3 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Mr. E. Martin Chamberlain
V.P. Regulatory Affairs
Ballard Medical Products
12050 Lone Peak Parkway
Draper, UT 84020Re: K990376
Ballard Medical Products@Faciletome™
Bow String Papillotome
Dated: February 5, 1999
Received: February 8, 1999
Regulatory Class: II
21 CFR 876.4300/Procode: 78KNS

Dear Mr. Chamberlain:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



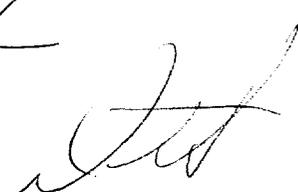
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Ballard Medical Products® Faciletome™ Bow String Papillotome

INTENDED USE STATEMENT

The Ballard Medical Products® Faciletome™ Bow String Papillotome(s) is intended to be used for patients requiring transendoscopic cannulation and sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi.

Prescription Over-the-Counter



(Division Sign-
Division of Re ctive, Abdominal, ENT,
and Radiologi vices
510(k) Numbe. K990376