

SEP 11 1998

Appendix F
Attachment 1.0



12050 Lone Peak Parkway
Draper, Utah 84020
(801) 572-6800
FAX (801) 572-6999

“Special” 510(k): Device Modification Premarket Notification Summary per 807.92(c)

Wednesday, August 12, 1998

- 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): MIC- KEY® “G”™ Low Profile Gastrostomy Replacement Kit
- Common Name per 807.92(a)(2): Enteral Feeding Catheter Kit
- Classification per 807.92(a)(2): MIC- KEY® “G”™ Low Profile Gastrostomy Replacement Kit has been classified a Class II device through the Gastrointestinal – Urology Panel per 21 CFR 876.5980. Classification name is Tubes, Gastrointestinal (and Accessories) – Product Code 78KNT.
- Legally marketed equivalent(s) per 807.92(a)(3): MIC-KEY® Low Profile Gastrostomy Kit #K922667/B.
- Description of the device 807.92(a)(4): The MIC-KEY® “G”™ Low Profile Gastrostomy Replacement Kit is intended to be used for patients requiring enteral support or decompression via a gastrostomy, and is designed to be a balloon – secured replacement gastrostomy tube. A tapered distal tip eases insertion through the gastric tract and the balloon is then inflated to assure secure placement. The tapered tip makes the tube less traumatic to place than skin level tubes with obturator placed mushroom type tips.

The balloon in this device is mounted (distal cuff) to the distal inner lumen of the feeding tube, the proximal cuff is mounted to the outer diameter of the feeding tube. While the balloon length is equivalent to the predicate MIC-KEY, the overall length of the device has been decreased to facilitate the balloon, when inflated, to surround the device distal tip.

The device is packaged sterile and is marketed with a number of accessories; reference Section 11 – Kit Certification, “Special” 510(k) Premarket Notification.

- Intended Use per 807.92(a)(5): The MIC- KEY® “G”™ Low Profile Gastrostomy Replacement Kit is intended to be used for patients requiring enteral support or decompression via a gastrostomy and is designed to be a balloon – secured replacement gastrostomy tube.

LALLARD
Medical Products

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- Technological Characteristics (equivalence to predicate devices) per 807.92(a)(6): Similarly, the aforementioned devices have commonality in their balloon and tubing material – Silicone. All three device kits, market, in their kits: Gauze pads, syringe(s) and feeding sets.
- Determination of Substantial Equivalence (non-clinical data) per 807.92(b)(1): The following in vitro tests were performed on the proposed MIC-KEY® "G"™ Gastrostomy Tube:
 - 1. Balloon Cuff Glue Bond Inspection
 - 2. Visual/Dimensional Inspection
 - 3. Balloon Burst Strength
- Conclusions from non-clinical data per 807.92(b)(3): Based on the indications for use, technological characteristics, and performance testing, the MIC-KEY® "G"™ Gastrostomy Tube has been shown to be safe and effective for its intended use.

Note: The testing of and acceptance criteria of the proposed device was identical to the testing and acceptance criteria of the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 1998

Mr. E. Martin Chamberlain
V. P., Regulatory Affairs
Ballard Medical Products
12050 Lone Peak Parkway
Draper, Utah 84020

Re: K982894
Ballard Mic-Key® "G"™ Low Profile
Gastrostomy Replacement Kit
Regulatory Class: II
21 CFR 876.5980/Procode: 78 KNT
Dated: August 12, 1998
Received: August 17, 1998

Dear Mr. Chamberlain:

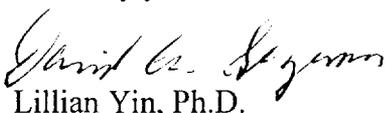
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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. 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 legally 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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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,

for 
Lillian Yin, Ph.D.

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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INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: MIC-KEY® "G"™ Low Profile Gastrostomy Replacement Kit

Indications for Use: The MIC-KEY® G™ Low Profile Gastrostomy Replacement Kit is designed as a replacement Gastrostomy tube. It can be used in any well formed gastric tract where a low profile device is considered desirable.

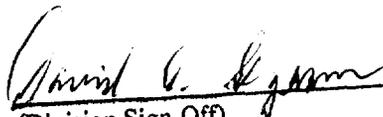
Gastrostomy tube feeding may be indicated for patients needing long term enteral support, including but not limited to, feeding, hydrating, medication delivery, and decompressing, secondary to a primary condition relating to the head or neck. These conditions include:

- Stroke
- Cancer
- Head or neck tumors, injuries, or trauma
- Neurological disorders resulting in a chewing or swallowing disorder.

(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


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982894