K061240

Sherlock™ Tip Location System (TLS) Detector
510(k) Summary (Page 1 of 1)

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Device trade name: Sherlock™ Tip Location System (TLS) Detector

Common name: Catheter Placement Verification Device

Device class and panel: 880.5970, Accessory to intravascular catheter, Class II

Applicant name:

Cynthia Pestka
Lucent Medical Systems, Inc.
811 Kirkland Ave, Suite 100
Kirkland, WA 98033
(425) 822-3310, x33 (phone)

Predicate device(s): K00099, Zortran Detector

Device description:

The Sherlock™ Tip Location System (TLS) Detector is a battery or line powered hand held device which detects the location of a magnet-tipped catheter stylet. A battery charger is also provided. The Sherlock™ Tip Location System (TLS) Detector uses only passive field sensors, and does not emit energy of any sort into the patient.

The Sherlock™ Tip Location System (TLS) Detector is designed (and labeled) to be used only with a compatible PICC or CVC intravascular catheter stylet which contains one or more small, specially oriented magnets encapsulated at the distal end. It provides rapid feedback to a caregiver about the location and orientation of these magnet-tipped devices during initial placement.

Premarket Testing:

Type	Characteristics Tested	Results
Bench	Accuracy	Meets accuracy claim
Bench	User interface	Meets requirements

™ Sherlock is a registered trademark of Bard Access Systems

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2006

Ms. Cindy Pestka
Director, Regulatory Affairs and Quality Assurance
Lucent Medical Systems Incorporated
811 Kirkland Avenue, Suite 100
Kirkland, Washington 98033

Re: K061240
Trade/Device Name: Sherlock™ Tip Location System (TLS) Detector
Regulation Number: 880.5970
Regulation Name: Percutaneous, Implanted Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: May 2, 2006
Received: May 3, 2006

Dear Ms. Pestka:

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment #3
Statement of Intended Use

Indications for Use Statement

510(k) Number (f known) K061240

Device Name Sherlock™ Tip Location System (TLS) Detector

Indications For Use The Sherlock™ Tip Location System (TLS) Detector quickly locates and confirms the position of specially designed, magnet-tipped Peripherally Inserted Central Catheters (PICCs) and Central Venous Catheters (CVCs) during initial placement. This device may be used by appropriate caregivers in hospitals, long-term care facilities or home-care settings.

The Sherlock™ Tip Location System (TLS) Detector provides rapid feedback to the caregiver, but was not designed to replace conventional methods of placement verification. Users are urged to confirm correct placement according to their established institutional protocol and clinical judgment.

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 _____
(Per 21 CFR 801.109)

[signature]
[illegible] Division of [illegible]ology, General Hospital,
[illegible]ion Control, Dental Devices
[illegible] K061240