MAR 1 - 2005

SECTION 2. SUMMARY AND CERTIFICATION

2.A. 510(K) SUMMARY

Submitter:	SterilMed, Inc.
Contact Person:	Dr. Bruce R. Lester SterilMed, Inc. 11400 73rd Avenue North Minneapolis, MN 55369 Ph: 763-488-3409 Fax: 763-488-3350
Date Prepared:	December 13, 2004
Trade Name:	SterilMed Reprocessed IVUS Imaging Catheter
Classification Name: and Number:	Angiography Catheter Class II, 21 CFR 870.1200
Product Code:	NLI
Predicate Device(s):	The SterilMed Reprocessed Imaging Catheter is substantially equivalent to the AcuNav™ Diagnostic Ultrasound Catheter Manufactured by Acuson Corp. (K992631).
Device Description:	The SterilMed Reprocessed Imaging Catheter is intended to be used with a compatible ultrasound imaging system. It is steerable, has a useable length of 90 cm and a diameter of 10 French. The distal end of the catheter contains an ultrasonic phased array imaging transducer. The transducer offers imaging modes at frequencies between 4.0 and 10.0 MHz.
Intended Use:	The SterilMed Reprocessed Imaging Catheter is intended for intravascular or intracardiac ultrasound imaging in order to provide visualization of vascular anatomy, cardiac and great vessel anatomy and physiology, or other devices in the heart. This device is intended for use in the right heart only.
Functional and Safety Testing:	Representative samples of reprocessed imaging catheters underwent design testing to demonstrate appropriate

functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced. Finally, testing to support the required Special 510(k) Report was successfully performed and provided to the Agency.

Conclusion:

The imaging catheters reprocessed by SterilMed are substantially equivalent to the AcuNav™ Diagnostic Ultrasound Catheter Manufactured by Acuson Corp. (K992631). This conclusion is based upon the fact that this device is identical to the predicate device in terms of its design, materials, indications for use, and construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 - 2005

SterilMed, Inc.
c/o Bruce Lester, Ph.D.
Vice President Research and Development
11400 73rd Avenue North
Minneapolis, MN 55369

Re: K043453
Trade Name: Sterilmed Reprocessed IVUS Imaging Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: NLI
Dated: December 13, 2004
Received: December 15, 2004

Dear Dr. Lester:

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) 276-0120 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/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Enclosure - List of Devices Substantially Equivalent

Orig Models found to be SE
Acuson (1)
55790

Indications for Use

510(k) Number (if known): K043453

Device Name: Reprocessed Imaging Catheters

Indications For Use:

The SterilMed Reprocessed Imaging Catheter is intended for intravascular or intracardiac ultrasound imaging in order to provide visualization of vascular anatomy, cardiac and great vessel anatomy and physiology, or other devices in the heart. This device is intended for use in the right-heart only.

Prescription Use __X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043453