SECTION 5: 510(k) Summary

K083189

Submitter: Avail Medical Products, Inc.
1900 Carnegie Avenue
Santa Ana, CA 92705

Contact: Hanumantha Hari
949-263-5060 ext. 267

NOV 21 2008

Name of Device: Steri-Lub™ Lubrication Gel

Predicate Device: Steri-Lub™ Lubrication Gel, K944969

Description of the New Device: The Steri-Lub™ Lubrication Gel is a sterile, single patient use, disposable instrument that is substantially equivalent to the predicate device and other pre-filled syringes. All Steri-Lub™ Lubrication Gel syringes are designed for lubrication of a body orifice to facilitate entry of a diagnostic or therapeutic device only and are intended for single patient use.

INTENDED USE OF THE NEW DEVICE: The Steri-Lub™ Lubrication Gel is intended to be used in procedures requiring a sterile product (surgical, urological). The Lubrication Gel is intended to be used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device.

Comparison of the Technological Features of the New [Modified] Device and Predicate Devices: The modified device and the lawfully marketed predicate device contain similar materials of construction.

Signed,

Hanumantha Hari
Vice President Quality and Regulatory Affairs
Avail Medical Products, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Patricia Anne Goeree
Regulatory Affairs Specialist
Avail Medical Products, Incorporated
1900 Carnegie Avenue
Santa Ana, California 92705

NOV 21 2008

Re: K083189
Trade/Device Name: Steri-Lub™ Lubrication Gel
Regulation Number: 21 CFR 880.6375
Regulation Name: Patient Lubricant
Regulatory Class: I
Product Code: KMJ
Dated: October 28, 2008
Received: October 30, 2008

Dear Ms. Goeree:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:___Steri-Lub ™ Lubricating Gel

Indications For Use:

The Steri-Lub Lubricating Gel is intended to be used in procedures requiring a sterile product (surgical and urological). The Lubrication Gel is intended to be used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K983189