Section 5 – 510(k) Summary

General Information

Owner's Name:	Spirus Medical, Inc.
Address:	1063 Turnpike Street Stoughton, MA 02072
Telephone Number:	(781) 297-5042
Fax Number:	(781) 297-5059
Contact Person:	Robert Ailinger

APR - 3 2008

Subject Device Name:	Spirus Medical Lubricant
Trade Name:	Spirus Medical Lubricant
Common/Usual Name:	Patient lubricant
Product Code:	KMJ
FDA Regulation:	21 CFR 880.6375 – Patient Lubricant
Device Classification:	Class I

Predicate Device Names:

Trade Name:	K-Y Lubricating Jelly (Johnson & Johnson, Inc.)
Common/Usual Name:	Patient lubricant
Product Code:	KMJ
FDA Regulation:	21 CFR 880.6375 – Patient Lubricant
Device Classification:	Class I
Premarket Notification:	K810310

Trade Name:	Probe Personal Lubricant (Davryan Laboratories, Inc.)
Common/Usual Name:	Condom & accessories
Product Code:	HIS
FDA Regulation:	21 CFR 884.5300 – Condom
Device Classification:	Class II
Premarket Notification:	K952464

Device Description
The Spirus Medical Lubricant is a water-based lubricant intended for lubrication of a body orifice to facilitate entry of a diagnostic or therapeutic device.

Indications for Use
For medical purposes to lubricate body orifices to facilitate entry of diagnostic or therapeutic devices.

Substantial Equivalence
Substantial Equivalence for the Spirus Medical Lubricant has been established by comparison of the chemical formula for the proposed device vs. that of the predicate devices. Biocompatibility testing was conducted on the finished device in accordance with ISO 10993.

Conclusion
The Spirus Medical Lubricant meets all the pre-determined acceptance criteria of the testing performed to confirm safety and effectiveness; the Spirus Lubricant is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 2008

Spirus Medical, Incorporated
C/O Ms. Pamela Papineau
President, Regulatory Affairs Consultant
Delphi Medical Device Consulting, Incorporated
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K080042
Trade/Device Name: Spirus Medical Lubricant
Regulation Number: 880.6375
Regulation Name: Patient Lubricant
Regulatory Class: I
Product Code: KMJ
Dated: December 30, 2008
Received: January 8, 2008

Dear Ms Papineau:

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.

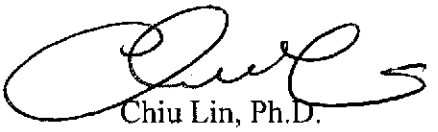
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

K080042

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Spirus Medical Lubricant

Indications for Use:

Intended for medical purposes to lubricate body orifices to facilitate entry of diagnostic or therapeutic devices.

Prescription Use _____ OR Over-the -Counter Use __X__
(Per 21 CFR 801 Subpart D) (Per 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
nfection Control, Dental Devices

10(k) Number: K080042