

APR - 9 1998

510(k) Premarket Notification  
Lubriscan Ultrasound Gel

## 10. 510(k) Summary

### Submitted By:

Michael Caswell, Ph.D.  
Cosmaceutical Marketing, Inc.  
10820 Alder Circle  
Dallas, TX 75238  
(214) 340-1503  
January 8, 1998

### Device:

Trade Name: Lubriscan Ultra Scan Gel +  
Common/Usual Name: Ultrasound Gel  
Proposed Classification: 892.1560 Ultrasound pulsed echo imaging system  
892.1570 Diagnostic ultrasound transducer

### Predicate Devices:

Lubriscan Ultra Scan Gel + is similar in terms of intended use, materials of construction, and technological characteristics to predicate devices reviewed as coupling gels used to couple ultrasound devices to surfaces such as skin.

### Device Description:

Lubriscan Ultra Scan Gel + is used for coupling ultrasound devices to external surfaces such as skin. The gel is not sterile. The raw materials comprising the gel have a long and established history as raw materials in cosmetics.

### Substantial Equivalence:

The device will be manufactured and packaged according to specified process controls and a Quality Assurance Program similar to pharmaceuticals currently manufactured and marketed by Cosmaceutical Marketing, Inc. The device is similar with respect to indications for use, materials and physical characteristics to predicate devices in terms of section 510(k) substantial equivalency.



Food and Drug Administration  
9200 Corporate Boulevard  
Bethesda, MD 20850

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Michael Caswell, Ph.D.  
Cosmaceutical Marketing, Inc.  
10820 Alder Circle  
Dallas, Texas 75238

Re: K980091  
Lubriscan® Ultra Scan Gel+  
Dated: January 8, 1998  
Received: January 9, 1998  
Regulatory class: II  
21 CFR 892.1570/Procode: 90 ITX

Dear Dr. Caswell:

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 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. 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 (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, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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,

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

**8.6 Statement of Indication for Use**

510(k) Number (if known): To Be Assigned

Device Name: Lubriscan® Ultra Scan Gel +

Indications for Use:

Lubriscan® Ultra Scan Gel + is intended to be used on external, intact skin for short duration as a coupling contact medium for abdominal and OB/GYN diagnostic scanning procedures.

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

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CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use   X    
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_