K052173

OCT 19 2005

510(K) SUMMARY FOR ORTHOVITA, INC.'S VITAGEL™ SURGICAL HEMOSTAT SPRAY SET

Submitter's Name, Address, Telephone Number, And Contact Person

Orthovita, Inc.
45 Great Valley Parkway
Malvern, PA 19355

Telephone: (610) 407-5251
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Contact: Gina M. Nagvajara, Ph.D.

Date Prepared

August 9, 2005

Name of the Device

Vitagel™ Surgical Hemostat Spray Set

Common or Usual Name

Piston syringe.

Classification Name

Piston syringe (FMF).

Predicate Devices

- Micromedics FibriJet Aerosol Applicator.
- Baxter Tissomat and Spray Set.

Intended Use

The Vitagel Spray Set Vitagel™ Application System is intended for use in the application (by spraying) of the two components of Vitagel™ Surgical Hemostat onto wound surfaces.

Technological Characteristics

The Vitagel Spray Set consists of a Spray Applicator and Filtered Tubing. The Spray Applicator is connected directly to the joiner of the dual syringe system supplied with the Vitagel preparation and application kit and is connected to a medical grade propellant gas control device via the Filtered Tubing. The Vitagel Spray Set aerosolizes the Vitagel for application to a suitable treatment site as described in the Vitagel instructions for use.

Performance Data

Bench testing demonstrates that the Vitagel Spray Set performs in a comparable manner to predicate devices. Animal testing confirms that application of Vitagel using the Vitagel Spray Set achieves results comparable to those obtained when Vitagel is applied using previously approved methods.

Substantial Equivalence

The Vitagel Spray Set has an intended use substantially similar to both the Micromedics FibriJet and the Baxter Tissomat, namely the application by spraying of two non-homogenous fluids.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2005

Dr. Gina M. Nagvajara
Vice President, US Regulatory Affairs
Orthovita, Incorporated
45 Great Valley Parkway
Malvern, Pennsylvania 19355

Re: K052173
Trade/Device Name: VITAGEL SURGICAL HEMOSTAT SPRAY SET
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: August 9, 2005
Received: August 10, 2005

Dear Dr. Nagvajara:

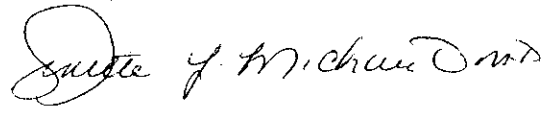
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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

Indications for Use

510(k) Number (if known): K052173

Device Name: Vitagel™ Surgical Hemostat Spray Set

Indications For Use:

The Vitagel™ Surgical Hemostat Spray Set is intended for use in the application (by spraying) of the two components of Vitagel™ Surgical Hemostat onto wound surfaces.

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

510(k) Number: K052173