K052090

AUG 5 - 2005

II. Summary of Safety and Effectiveness

Splash!® Dental Impression Material

1. Date of Summary:

2. Date of Summary Preparation: July 15, 2005

3. Submitting Firm: Discus Dental, Inc.

4. Contact Person

Suzanne Ridgway
Regulatory Affairs Coordinator

Discus Dental, Inc.
8550 Higuera Street
Culver City, CA 90232
310.845-8345 - phone
310.845.8647 - fax

5. Name of Medical Device

Proprietary Name: Splash!® Dental Impression Material

Common/Usual Name: Dental Impression Material

Classification Name: Impression Material

6. Description of Medical Device

Splash!® Dental Impression Material is an addition-reaction base/catalyst polyvinylsiloxane dental impression material. It is available in Regular set or fast-setting Half-time varieties. Both are available in a heavy viscosity and in wild berry flavor, as well as unflavored.

7. Intended Use

Splash!® Dental Impression Material is intended for use with all crowns, bridges, occlusal and dental implant impression techniques to reproduce the structure of a patient's teeth and gums.

8. Substantial Equivalence Determination

Evaluations and in-house testing of the new Splash!® Dental Impression Material device by Discus Dental, Inc. have shown this device to be substantially equivalent to the following commercially marketed impression materials:

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Predicate Device (Primary)	**Company**	**510(k) No.**
Precision VPS Impression Material	Discus Dental	K040053

Predicate Device (Secondary)	**Company**	**510(k) No.**
P2 Polyether	Heraeus Kulzer Inc	K030318
Aquasil Smart Wetting Impression Material	Denstply, Intl.	K021416

Predicate Similarities

Product	Company	ISO 4823	Recovery from Deformation	Shrinkage	Storage Conditions
Splash!	Discus Dental	Type 0-3	99.2- 99.5%	Max. <0.10%	59° -78° F (15° -25° C)
Aquasil	Dentsply	Type 1-3	>98.0%	<0.50%	65° -80° F (18° -25° C)
P2 Polyether	Heraeus Kulzer	Type 1-3	97.5 – 98.0%	0.40 – 0.50%	65° -80° F (18° -25° C)
Precision	Discus Dental	Type 0 -3	99.3- 99.6%	Max. 0.10%	59° -78° F (15° -25° C)

Predicate Differences

Product	Company	Working time	Hardness (Shore A)	Strain in Compression	Shrinkage	Storage Conditions
Splash!	Discus Dental	55 sec – 65 sec	62- 67	2.3 – 2.5%	Max. <0.10%	59° -78° F (15° -25° C)
Aquasil	Dentsply	75 sec – 105 sec	Data Not Available	1 – 5%	<0.50%	65° -80° F (18° -25° C)
P2 Polyether	Heraeus Kulzer	120 sec.	44 - 64	4.3 – 10%	0.40 – 0.50%	65° -80° F (18° -25° C)
Precision	Discus Dental	45 – 105 sec	44 – 69	2.1 – 4.5%	0.10%	59° -78° F (15° -25° C)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 5 - 2005

Discus Dental, Incorporated
C/O Dr. Alfredo J. Quattrone
Responsible Third Party Official
California Department of Health Services
Food & Drug Branch
P.O. Box 997 413
Sacramento, California 95899-74413

Re: K052090
Trade/Device Name: Splash! Impression Material Device
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: July 26, 2005
Received: August 2, 2005

Dear Dr. Quattrone:

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

V. Indications for Use Statement

510(k) Number: K052090

Device Name: Splash! Impression Material

Intended Use

Splash!® Dental Impression Material is intended for use with all crowns, bridges, occlusal and dental implant impression techniques to reproduce the structure of a patient's teeth and gums.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
Per 21 CFR Section 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K052090