K093587

510(k) Summary

JAN 21 2010

Trade Name: **Dental Mercury**

Sponsor:
DMG USA, Inc.
23 Frank Mossberg Drive
Attleboro, MA 02703
Registration # not yet assigned
Owner/Operator No. 9005969

Subject Device:
Device Name: Dental Mercury
Classification/Regulation: ELY – Dental Mercury
21 CFR 872.3700; Class II

Product Description
Dental Mercury is elemental mercury, supplied as a liquid packaged in sachets.

Indications for Use:
Dental Mercury is elemental mercury, supplied as a liquid packaged in sachets, intended to be combined with amalgam alloy for the direct filling of carious lesions or structural defects in teeth.

The proposed Dental Mercury meets the requirements included in the following consensus standards and FDA guidance documents:

1. ***ISO 24234:2004(E) Dentistry - Mercury and alloys for dental amalgam - First edition***
2. ***Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy - Guidance for Industry and FDA Staff (July 28, 2009)***

Predicate Devices:
The components of the proposed Dental Mercury are substantially equivalent to several currently marketed products including the following:

Dental Mercury:

Product Name	Predicates
MERCURY DENTAL	K973548; ALEACIONES DENTALES ZEYCO, S.A. DE C.V.
DENTAL-QUECKSILBER	K902388; DEGUSSA AG

Safety and Performance:
This submission is an Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), DMG-USA has provided information to demonstrate conformity with FDA's guidance document entitled:

Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy - Guidance for Industry and FDA Staff (July 2009)

Conclusion:

Based on the indications for use, technological characteristics, and comparison to the predicate devices, the Dental Mercury has been shown to meet the requirements established in FDA's Class II Special Controls guidance document, and to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 21 2010

DMG USA, Incorporated
C/O Ms. Pamela Papineau
Consultant
23 Frank Mossberg Drive
Attleboro, Massachuttes 02703

Re: K093587
Trade/Device Names: Dental Mercury
Regulation Number: 21 CFR 872.3700
Regulation Name: Dental Amalgam, Mercury, and Amalgam Alloy
Regulatory Class: II
Product Code: ELY
Dated: November 18, 2009
Received: November 19, 2009

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K093587

Device Name: **Dental Mercury**

Indications for Use:

Dental Mercury is elemental mercury, supplied as a liquid packaged in sachets, intended to be combined with amalgam alloy for the direct filling of carious lesions or structural defects in teeth.

Prescription Use X OR Over-the -Counter Use ____

(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)

RSBetz DDS for Dr K.P. Mudry (Acting)

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K093587