FEB 14 2011

K103244

DENTSPLY

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World Headquarters
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SECTION 5. 510(k) SUMMARY

for

QMix™ 2in1 Endodontic Irrigating Solution

1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

Date Prepared: 01 February 2011

2. Device Name:

- Proprietary Name: QMix™ 2in1 Endodontic Irrigating Solution
- Classification Name: Cleanser, Root Canal
- CFR Number: N/A
- Device Class: Unclassified
- Product Code: KJJ

3. Predicate Device:
BioPure MTAD Root Canal Cleanser, DENTSPLY International, K053167

4. Description of Device:
QMix™ 2in1 Endodontic Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system by removing the smear layer and killing bacteria after endodontic instrumentation.

5. Indications for Use:
QMix™ 2in1 Endodontic Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system after endodontic instrumentation.

6. Description of Safety and Substantial Equivalence:
Technological Characteristics.
All of the components found in QMix™ 2in1 Endodontic Irrigating Solution have been used in legally marketed devices and were found safe for dental use. We believe that prior use of components in legally marketed devices, the performance and biocompatibility data provided support the safety and effectiveness of QMix™ 2in1 Endodontic Irrigating Solution for the indicated uses.

Non-Clinical Performance Data.
The efficacy and biocompatibility of QMix™ 2in1 Endodontic Irrigating Solution was demonstrated *via* non-clinical *in vitro* and *ex vivo* studies.

Clinical Performance Data.
No clinical studies were conducted on this device.

Conclusion as to Substantial Equivalence
QMix™ 2in1 Endodontic Irrigating Solution, to be manufactured by DENTSPLY International, is substantially equivalent to the currently cleared and marketed BioPure MTAD root canal cleanser.

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

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, Pennsylvania 17405

FEB 14 2011

Re: K103244
Trade/Device Name: QMix™ 2in1 Endodontic Irrigating Solution
Regulatory Class: Unclassified
Product Code: KJJ
Dated: February 1, 2011
Received: February 2, 2011

Dear Ms. Lewis:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K103244

Device Name: QMix™ 2in1 Endodontic Irrigating Solution

Indications for Use:

QMix™ 2in1 Endodontic Irrigating Solution is a premixed dual-action device that cleanses and disinfects the root canal system after endodontic instrumentation.

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

510(k) Number: K103244