K092614

DENTSPLY

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DEC - 2 2009

510(k) Summary
for
X-Smart Easy

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: 18 August 2009

2. Device Name:

   Proprietary Name: X-Smart Easy
   Classification Name: Dental Handpiece and Accessories
   CFR Number: 872.4200
   Device Class: I
   Product Code: EKX

3. Predicate Device:

   Prophy-Mate and Endo Mate Motor Handpiece (K990682)

4. Description of Device:

   The X-Smart Easy is an electric motor-driven handpiece intended for root canal preparation procedures in endodontic industry.

5. Indications for Use:

   X-Smart Easy is designed for use by dentists in standard endodontic procedures using rotary endodontic files and rotary endodontic drills (Gates-Glidden).

6. Description of Safety and Substantial Equivalence

   Technological Characteristics

   Patient contact elements of the components found in X-Smart Easy have been used in legally marketed devices and/or were found safe for dental use.

Non-Clinical Performance

Biocompatibility Testing

Cytotoxicity, sensitization and irritation testing were performed in accordance with ISO 10993. All patient contact components demonstrated biocompatibility.

Electromagnetic Compatibility and Electrical Safety

The X-Smart East conforms to UL60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety; IEC 60601-1-2 Medical Electrical Equipment, Part 1-2: General Requirements for Safety Collateral Standard Electromagnetic Compatibility; and IEC 61000-3-2 Electromagnetic Compatibility (EMC) Part 3: Limits – Section 3: Limitations of Voltage Fluctuations.

Conclusion as to Substantial Equivalence

The X-Smart Easy is substantially equivalent to the Prophy Mate and Endo Mate Handpiece (K990682) based on equivalence of the intended use, similar features and technical characteristics. Performance testing was performed to validate the safety and effectiveness of the X-Smart Easy, which included electrical safety, electromagnetic compatibility, and validation testing of both hardware and software functions. The X-Smart Easy does not raise any new issues of safety, effectiveness, or performance of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Helen Lewis
Director
DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17404

DEC - 2 2009

Re: K092614
Trade/Device Name: X-Smart Easy
Regulation Number: 21CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: November 24, 2009
Received: November 25, 2009

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.

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

Susan Runner, D.D.S., M.A.
Acting Division 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 Statement

510(k) Number (if known): K092614

Device Name: X-Smart Easy

Indications for Use:

X-Smart Easy is indicated for use by dentists in standard endodontic procedures using rotary endodontic files and rotary endodontic drills (Gates-Glidden).

Prescription Use X	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(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)

Kevin Mulley for NSR

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

510(k) Number: K092614