K103653

MAY 2 6 2011

SECTION 5. 510(k) SUMMARY
for
e3 Torque Control Motor

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: 10 December 2010

2. Device Name:

- Proprietary Name: e3™ Torque Control Motor
- Common Name: dental motor
- Classification Name: Dental Handpiece and Accessories
- CFR Number: 872.4200
- Device Class: I
- Product Code: EKX

3. Predicate Device:

X-Smart™ Easy, K092614

4. Description of Device:

The e3 Torque Control Motor is an electric motor-driven handpiece intended for root canal preparation procedures in the endodontic industry. It works in both reciprocating mode and continuous rotation. This motor is provided with pre-programmed settings for nickel titanium rotary file systems sold by DENTSPLY. The motor also allows the dentist to program 15 settings of their choice for speed and torque control.

The device consists of a control unit with an LCD screen for selection of settings. A foot pedal is connected to the control unit so the dentist can selectively activate and deactivate the motor. A power supply is also connected to the control unit to charge the battery. The motor is connected to the control unit and a 6:1 contra angle attaches to the motor. This angle is cleared under K972436. Files attach to the contra angle.

5. Indications for Use:

The e3 Torque Control Motor is a medical device designed for use by dentists for use with dental root canal instruments in continuous rotation with torque control or in reciprocating movement.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics

The technological similarities of the two devices are as follows:

- Both meet the requirements for Biocompatibility per ISO 10993, the Electromagnetic Compatibility and Electrical Safety Requirements conforming to EN 60601-1 and EN 60601-1-2, and EN 60601-1-8.

- Both devices meet the requirements for Software Validation per EN 62304.

- Both devices have the same type of power source- battery with AC charger.

- Both devices have a torque control feature which prevents the rotary file from exceeding its required torque strength.

The e3 Torque Control Motor (subject device) and the X-Smart Easy motor (predicate device) have minor technological differences:

- The X-Smart East Motor has a cordless handpiece. The e3 Torque Control Motor has a cord attachment to the handpiece.

- The X-Smart Easy motor is designed for continuous rotation motion only. The e3 Torque Control Motor is designed for both continuous rotation as well as reciprocating motion.

- The gear ratios for the contra angles are different for the two devices.

- The e3 has a USB port for software update capabilities via the manufacturer.

- The X-Smart East motor has a push button on the handpiece for motor operation. The e3 Toque Control Motor can be operated with either the foot pedal or the console.

- The console house for the X-Smart Easy is ABS- the e3 console housing is a PC/ABS blend.

Non-Clinical Performance Data.

Biocompatibility Testing
Cytotoxicity was performed for the Sirona Endo 6:1 contra angle in accordance with ISO 10993. All patient contact components demonstrated biocompatibility.

Electromagnetic Compatibility and Electrical Safety
The e3 Torque Control Motor conforms to EN 60601-1: 2007 Medical Electrical Equipment, Part 1: General Requirements for Safety, EN 60601-1-8:2007 Guidance For Alarm Systems In Medical Electrical Equipment and Medical Electrical Systems, and EN 60601-1-2:2007 Electromagnetic Compatibility – Requirements and Tests

Software validation
Both devices meet software validation requirements per EN 62304.

Clinical Performance Data.
Not Applicable

Conclusion as to Substantial Equivalence

The e3 Torque Control Motor is substantially equivalent to the X-Smart Easy (K092614) based on equivalence of the intended use, the non-clinical performance data and technological characteristics. Performance testing data of the e3 Torque Control Motor was compared to the safety and effectiveness of the X-Smart Easy. This included electrical safety, electromagnetic compatibility, and non-clinical performance testing of both hardware and software functions. The e3 Torque Control Motor does not raise any new issues of safety, effectiveness, or performance of the product when compared to the X-Smart Easy. These test results support a determination of substantial equivalence.

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
Dentsply International, Incorporated
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17404

MAY 26 2011

Re: K103653
Trade/Device Name: e3 Torque Control Motor
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBW
Dated: May 19, 2011
Received: May19, 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,

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): K103653

Device Name: e3 Torque Control Motor

Indications for Use:

The e3 Torque Control Motor is a medical device designed for use by dentists for use with dental root canal instruments in continuous rotation with torque control or in reciprocating movement.

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)

Susan Runner

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

510(k) Number: K103653