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Summary of Safety and Effectiveness – "510 (k) Summary"

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMD 1990 and CFR 807.92.

SUBMITTER INFORMATION

a.	Company Name	SATELEC
b.	Company Address	17 Avenue Gustave Eiffel BP 30216 33708 Merignac Cedex France
c.	Company phone	+01133556340607
	Company fax	01133556349292
d.	Contact Person	Rick Rosati Satelec c/o ACTEON, Inc. 124 Gaither Drive, Suite 140 MT Laurel, NJ 08054 Tel : 800 289-6367 ext 39 Fax : 856 222-4726 Email : Rick.Rosati@us.acteongroup.com
e.	Date Summary Prepared	November, 11, 2011

DEVICE IDENTIFICATION

a.	Trade/Proprietary Names:	I-ENDO DUAL
b.	Common name	Dental Motor
c.	Classification Name	Dental Handpiece and Accessories
d.	CFR Number	872.4200
e.	Device Class	I
f.	Product Code	EBW

IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
Dentsply Int.	E3 Torque Control Motor	K103653	26 May. 2011

DEVICE DESCRIPTION

The I ENDO DUAL 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.
The motor allows the dentist to program **10** settings of their choice for speed and torque control in rotating mode and to program 10 setting of their choice for speed and angles in reciprocating mode.
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.

INDICATIONS FOR USE

The I ENDO DUAL 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.

SUBSTANTIAL EQUIVALENCE

The I-ENDO DUAL is substantially equivalent to the E3 Torque Control Motor in commercial distribution by Dentsply International.

The fundamental technical characteristics of the I-ENDO DUAL are similar to those of the predicate device and are listed on the comparison chart provided in this 510(k) submission.

TECHNICAL CHARACTERISTICS

I-ENDO DUAL was designed and developed to provide a microprocessor controlled endodontic system with similar performances compared to predicate device.
I-ENDO DUAL :

- is equivalent in functions to the predicate device,
- has adjustable speeds and torque values (related to the reduction rate of the handpiece selected) that are fully customisable by the end user,
- has automatic motor shutdown/autoreverse system which provides to switch off/reverse the motor whenever set torque is reached,
- has reciprocating movements fully customizable.

PERFORMANCE DATA

I-ENDO DUAL was tested in accordance with the technical requirements of IEC 60601-1 and IEC 60601-1-2.

All evaluation of the I-ENDO DUAL were performed by Notified Laboratory, and all the results comply to standard listed below.

The conclusions drawn from the performance test are that I-ENDO DUAL comply with:

- IEC 55011 EMC Conducted RF emissions
- IEC 60529 Degrees of protection provided by enclosures (IP Code)
- IEC 60601-1 Medical Electrical Equipment Part 2,"Genaral Safety Norms"
- IEC 60601-1-2 Medical Electrical Equipment Part 1 EMC
- IEC 61000-4-2 EMC Electrostatic Discharge Immunity
- IEC 61000-4-3 Radiated RF immunity

- IEC 61000-4-4 Fast Transient Immunity
- IEC 61000-4-5 Pulse immunity
- IEC 61000-4-6 Conducted RF immunity
- IEC 61000-4-11 Supply Voltage Hole Immunity
- ISO 11498:1997 Dental handpieces – Dental low-voltage electrical motors

510(k) CHECKLIST

This notification contains all information required by 21 CFR 807.87.

A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

CONCLUSION AS TO SUBSTANTIAL EQUIVALENCE

I-ENDO DUAL is substantially equivalent to the the E3 Torque Control Motor (K103653) based on equivalence of the intended use, the non-clinical performance data and technological characteristics. Performance testing data of the I-ENDO DUAL was compared to the substantially equivalent of the E3 Torque Control Motor (K103653). This included electrical safety, electromagnetic compatibility, and non-clinical performance testing of both hardware and software functions. The I-ENDO DUAL does not raise any new issues of substantially equivalent or performance of the product when compared to the E3 Torque Control Motor (K103653. 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

SATELEC-ACTEON Group
C/O Mr. Rick Rosati
Quality Manager
ACETON, Incorporated
124 Gaither Drive, Suite 140
Mt Laurel, New Jersey 08054

JAN 1 0 2012

Re: K111623
Trade/Device Name: I-ENDO DUAL
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBW
Dated: January 2, 2012
Received: January 4, 2012

Dear Mr. Rosati:

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

Indication for use Statement

510(k) Number: K111623
To be assigned by FDA

Device Name: Endodontic Micromotor

Model: **I-ENDO DUAL**

Indications for Use: I-Endo Dual is indicated for use by dentists in standard endodontic procedures using endodontic files and endodontic drills.

(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 801.109)

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

510(k) Number: K111623