K133151

Section 06 – 510(k) Summary (SMDA Requirements)

JAN 16 2014

This Summary of Safety And Effectiveness is submitted in accordance with 21 CFR 807.92.c.

1 – Administrative Information

1- a. Type of 510(k) submission:

These documents constitute a Traditional 510(k) Submission.

1- b. Submission date: April 3, 2013

1-c. 510(k) Submitter:

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1- e. Establishment registration number: 8044015

Section 06 – 510(k) Summary (SMDA Requirements)

2 – Device Information

2-a. Common Name of device:	Dental Handpiece and Accessories
2-b. Trade Name of device:	ENDO CENTER
2-c. Classification regulation:	Class II device
2-e. Medical Device Class:	II
2-f. Panel:	Dental
2-g. Product code:	EKX, ELC

3 – Identification of legally marketed device(s)

The Substantial Equivalence (SE) of the New Device is based on the Predicate Devices identified in the Table 01.

Table 01 – Identification of legally marketed devices

	Predicate Device (for Motor)	**Predicate Device (for Ultrasonic)**
Device name	I-ENDO DUAL	SUPRASSON P5 NEWTRON
Sponsor	BYDENTAL-Acteon Group	SATELEC-Acteon Group
Address	Via Vecchia Provinciale Lucchese, 49/F 51030 SERRAVALLE PISTOIESE (PT) ITALY	17 Avenue Gustave Eiffel BP 30216 33708 Merignac Cedex France
Intended use	For use by dentists in standard endodontic procedures using rotary endodontic files and rotary endodontic drills	For use by dentists in periodontics, endodontics, scaling, prosthesis procedures with ultrasonic tips

Section 06 – 510(k) Summary (SMDA Requirements)

	Predicate Device (for Motor)	Predicate Device (for Ultrasonic)
K number	K111623	K050895
Product code	EKX	ELC

I-ENDO DUAL (K1116231) device is used as predicate for root canal treatment with rotary and reciprocating files claims for the New Device

SUPRASSON P5 NEWTRON (K050895) is used as predicate for root canal treatment with ultrasonic tips claims for the New Device.

4 – Description of the Device

The ENDO CENTER is an electric motor-driven handpiece combined with an ultrasonic scaler intended for root canal preparation procedures in endodontic industry.

In ULTRASONIC mode, the device is able to drive piezo-electric resonator for root canal treatment at selectable power and fixed frequency .

In ROTATING mode, the device is able to drive electrical micromotor for rotary files for root canal treatment at selectable speed and torque.

In RECIPROCATING, mode, the device is able to drive electrical micromotor for reciprocating files for root canal treatment at selectable speed and rotational angle.

The New Device is a combination of two existing devices already in consolidated use in endodontic field.

TABLE 2

Main Design Characteristics of New Device

Ultrasonic	NEWTRON module as ultrasonic generator
Frequency	28 ÷36 kHz
Micromotor	1,000 ÷10,000 rpm at motor shaft
Torque Max	6,8 mNm at the shaft
Keyboard	Membrane keys, no LEDs
Display	Characters 4x20 back lighted
Cables' length	2,5 m
Ultrasonic Hand piece dimension	L = 200 mm x W = 28 mm x H = 24 mm
Ultrasonic Hand piece weight	78g
Micromotor handpiece weight	80g
Working temperature	10 -40°C (50-104°F)
Power supply	External Supplier in 100-240 V 50 60 Hz out 24VDC

5 – Intended Use

For use by dentists in standard endodontic procedures using rotary endodontic files or reciprocating endodontic files or use by dentists in periodontics, endodontics, scaling, prosthesis procedures with ultrasonic tips.

Section 06 – 510(k) Summary (SMDA Requirements)

6- Technological characteristics of the New Device compared to the Predicate Devices

6.1 Technological characteristics of the New Device compared to the Predicate Devices for endodontic treatment.

The predicate devices are :

- I-ENDO DUAL (K1116231, January 10, 2012)
- SUPRASSON P5 NEWTRON (K050895, April 20, 2005)

Technological perspective:
The New Device and the Predicate Devices use the same technology (Micromotor, Piezoelectric resonator) and the same technical concept.

Material perspective:
The New Device and the Predicate Device are extremely similar because they both share the external housing material, and the same handpieces.

Design perspective:
The New Device and the Predicate Device use the same:
- Electronic board.
- Electronic Ultrasonic control (NEWTRON)
- Accessories

Energy source perspective:
The New Device and the Predicate Device:
- Use external power supply AC/DC adapter.
- Deliver the same output energy source (Mechanical torque, ultrasonic vibration).

Material in contact with the patient:
Because of the New Device and the Predicate Device use the same tips and the same handpieces, the materials in contact with the patient are exactly the same.

Section 06 – 510(k) Summary (SMDA Requirements)

7 - Determination of substantial equivalence

The New Device joints in the same casing two devices used in endodontic since many years for use in root canal treatment.
The New Devices was born by the needs of practitioners that often use the two different devices in the same session.
During the development of the endo unit I-ENDO DUAL, assumed as predicated device, the design reserved some resources, not implemented, in order to be able in a near future to join a ultrasonic module (P5 NEWTRON) and a peristaltic pump, as in use in our implant unit for physiodispenser.
The New Device is not a new way to treat the root canal, but gives to the dentists the facility to use the device they need saving space around the patient.
The indications for use are the same of the micromotor and ultrasonic indications and the handpieces and accessories are the same too.

From external structure perspective, the New Device use the same casing of I-ENDO DUAL, made in self-extinguishing material (UL94-V0). Moreover, the materials in contact with the patient are exactly the same of both Predicate Devices.

Discussion of the non-clinical Tests:

The aim of the evaluation was to demonstrate the Substantial Equivalence between New Device and the selected Predicate Devices in terms of Performances.

The evaluated Performances were:
- Ultrasonic frequency
- Motor speed
- Motor torque

These information are located at section 18, Performance testing-Bench.

After tests, the obtained results for the New Device have been directly compared to the Predicate Device Performances. The results of the comparison show that the Performances of the New Device and the Predicate Device are similar.

Discussion of the safety Tests:

And on safety point of view:
The device has been tested using the following standard:

The Electromagnetic Compatibility has been performed according to
- IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3). (General) (Recognition Number: 5-53).

Section 06 – 510(k) Summary (SMDA Requirements)

The Electrical Safety has been performed according to:
- IEC 60601-1: Edition 3.0 2006 Medical Electrical Equipment - Part 1: General Requirements for Safety, (Edition 3). (General) (Recognition Number: 5-4).

No clinical evaluation is required

8 - Conclusion

The New Device is the same as the I-ENDODUAL and SUPRASSON P5 NEWTRON identified Predicate Devices in terms of Indication For Use
The ENDO CENTER indications for use are the same of I-ENDO DUAL for use by dentists in standard endodontic procedures using rotary endodontic files and rotary endodontic drills when used as a motor, and indications for use are the same of SP NEWTRON for driving ultrasonic tips during endodontic procedures as scaling, prosthesis conservative/restorative, ultrasonic endodontic treatment, ultrasonic periodontal treatment when used as a scaler .

The ENDO CENTER is the same as I-ENDO DUAL (k 111623) predicate device in terms of technology and design as both share the same PCB and the same components of software regarding motor driving, more the ENDOCENTER includes inside the NEWTRON Module that is the core of SUPRASSON P5 NEWTRON (K050895).
The selection of working function as rotational excludes the ultrasonic and viceversa, so ENDO CENTER can be configured or as micromotor or as ultrasonic scaler.

The ENDO CENTER is not a clinical innovation and the use is very well known by the practitioners. The ENDO CENTER is the same as the identified predicates in terms of clinical application. Also the used technologies and characteristics are similar to the predicates. The characteristics of the ENDO CENTER used with recommended dental procedures do not affect the Safety of the patients or of the operator. Moreover, the Effectiveness is the same as of the predicates.

End of Section

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 16, 2014

Satelec-Acteon Group
Rick Rosati
c/o ACTEON, Inc.
124 Gaither Drive, Suite 140
Mt. Laurel, NJ 08054

Re: K131151
Trade/Device Name: EndoCenter
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC, EKX
Dated: December 13, 2013
Received: December 13, 2013

Dear Rick 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 **[OIR/IVD OPTION] and Part 809**); 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 **[OIR/IVD OPTION] and Part 809**), please contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Kwame O. Ulmer -S for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 05 – Indication for Use

Indications for Use

510(k) Number (if known): K131151
(to be assigned by FDA)

Device Name: ENDOCENTER

Indications for Use:

For use by dentists in standard endodontic procedures using rotary endodontic files or reciprocating endodontic files or use by dentists in periodontics, endodontics, scaling, prosthesis procedures with ultrasonic tips.

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)

Mary S. Runner -S
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