



Food and Drug Administration
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July 2, 2015

Sirona Dental Systems GmbH
c/o Mr. Kofi Aninakwa
Sirona Dental Systems, Inc.
30-30 47th Avenue, Suite 500
Long Island City, New York 11101

Re: K150750

Trade/Device Name: Contra-Angle Handpieces: Endo 6:1, Ti Line Endo 6L, SironiTi Apex
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories
Regulatory Class: I
Product Code: EGS
Dated: May 22, 2015
Received: May 26, 2015

Dear Mr. Aninakwa:

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 contact the Division of Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

 Tina
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K150750

Device Name: CONTRA-ANGLE HANDPIECES : Endo 6:1, TI LINE Endo 6 L, SIRONiTi APEX

Indications for Use:

The contra-angle handpieces are used to hold and drive burr instruments for the purposes of rotary processing. The handpieces are intended for dental applications in endodontics and for root canal measurement and are used by trained dental personnel in dental practices and laboratories. The T1 Spray is intended to be used to clean and lubricate dental handpieces.

Prescription Use X
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
for
Sirona Dental Systems
CONTRA-ANGLE HANDPIECES

1 SPONSOR

Sirona Dental Systems GmbH
Fabrikstrasse 31
D-64625 Bensheim
Germany

Contact Person: Kofi Aninakwa
Telephone: 718-482-2248
Date Prepared: July 1st 2015

2 DEVICE NAME

Proprietary Names : Contra-Angle Handpieces: ENDO 6:1 / T1 LINE ENDO 6
L / SIRONiTi Apex.
Cleaner and Lubricant: T1 Spray
Common/Usual Name: Handpiece, Contra- And Right-Angle Attachment, Dental
Classification Name : Dental handpiece and accessories
Regulation Number : 21 CFR 872.4200
Product Code : EGS
Classification : II

3 PREDICATE DEVICES

Predicate Devices:

Root Canal Treatment:

- K090931 – “W&H ENTRAN
- K031204 – “Morita DENTAPORT ZX
- K103653 – “Dentsply E3 Torque Control Motor

Root Canal Measurement Support:

- K031204 – “Morita DENTAPORT ZX
- K042822 – “Nouvag TCM Endo V

T1 Spray

- K113674 – “Spray & Clean Handpiece Cleaner & Lubricant Maxima Handpiece Cleaner & Lubricant EZOARE Handpiece Cleaner & Lubricant” (3 trade names carry the same chemical formula)

The primary predicate device is the DENTAPORT ZX (K031204). The reference

predicates are K090931, K103653, K042822, and K113674.

4 INTENDED USE

The contra-angle handpieces are used to hold and drive burr instruments for the purposes of rotary processing. The handpieces are intended for dental applications in endodontics and for root canal measurement and are used by trained dental personnel in dental practices and laboratories. The T1 Spray is intended to be used to clean and lubricate dental handpieces.

5 DEVICE DESCRIPTION AND FUNCTION

ENDO 6:1

Endo 6:1 is a contra-angle handpiece which is adapted to dental electric motors or dental air motors with the ISO 3964 interface. It is reusable and it does not have a fiber optic light system.

- Extra small head for better access to preparation site
- Depth measurement in conjunction with an apex locator

T1 LINE ENDO 6 L

The T1 LINE ENDO 6 L contra-angle handpiece is equipped with a fiber optic light system. It is also adapted to dental electric motors or dental air motors with the ISO 3964 interface. It is reusable.

Features of T1 LINE ENDO 6 L:

- Extra small head for better access to preparation site
- Depth measurement in conjunction with an apex locator

SIRONiTi APEX

The SIRONiTi APEX contra-angle handpiece is adapted to dental electric motors with the ISO 3964 interface. It is reusable.

SIRONiTi APEX is equipped with a torque limitation function. Once a set torque has been reached, a gold plated magnetic coupling prevents jamming of the file in the root canal by retro-rotation.

Features:

- For NiTi files systems
- No jamming of the file in the root canals
- Torque level can be easily set
- For electric motors
- Extra small head for better access to preparation site
- Depth measurement in conjunction with an apex locator

T1 Spray

This is the lubricant used for maintenance and cleaning of the drive channels of the handpieces.

6 TECHNOLOGICAL CHARACTERISTICS SUMMARY

The overall design of the Sirona contra-angle handpieces is similar to the design of the predicate handpieces in that the predicate devices have similar indications for use and material composition as Sirona’s contra-angle handpieces and include similar features, operating parameters, dimensions and functional requirements. The primary predicate device is the DENTAPORT ZX (K031204). The reference predicates are K090931, K103653, K042822, and K113674. Whereas Sirona’s T1 LINE ENDO 6L has a light to illuminate the treatment area and is composed of mostly titanium, the predicate devices, Sirona’s ENDO 6:1 and SIRONiTi Apex do not have any illumination light and are composed of Stainless Steel*. Morita’s Dentaport ZX has a light function for polymerization. SIRONiTi Apex and ENDO 6:1 have the same head heights as the E3 Torque Control Motor and the head height of T1 LINE ENDO 6 L (12.2mm) is similar to the head height of DENTAPORT ZX (12.5mm). Sirona’s device Indications for Use align with the indications for use of the primary predicate.

Sirona’s devices are used by trained dental personnel and practices/laboratories for

- Root canal treatment and
- Root canal measurement

while Morita’s DENTAPORT ZX and TCM Endo V are used for

- Root canal treatment and
- Root canal measurement

The other predicates have similar indications for use except the ENTRAN EB-300 which has no root canal (Apex) measurement function. Overall, the Sirona’s instruments and the predicates have similar intended use. Finally, Sirona’s accompanying T1 Spray has nearly identical indications for use as K113674.

*TCM Endo V composition not available.

Below is a comparison of the dental handpieces to the predicate devices:

Endodontic contra-angle handpieces	Sirona	Sirona	Sirona
Product Designation	Endo 6:1	SIRONiTi Apex	T1 LINE ENDO 6 L
Operating Principle	straight and contra-angle handpiece	straight and contra-angle handpiece	straight and contra-angle handpiece

Indications for Use	The contra-angle handpieces are used to hold and drive burr instruments for the purposes of rotary processing. The handpieces are intended for dental applications in endodontics and for root canal measurement and are used by trained dental personnel in dental practices and laboratories. The T1 Spray is intended to be used to clean and lubricate dental handpieces.	The contra-angle handpieces are used to hold and drive burr instruments for the purposes of rotary processing. The handpieces are intended for dental applications in endodontics and for root canal measurement and are used by trained dental personnel in dental practices and laboratories. The T1 Spray is intended to be used to clean and lubricate dental handpieces.	The contra-angle handpieces are used to hold and drive burr instruments for the purposes of rotary processing. The handpieces are intended for dental applications in endodontics and for root canal measurement and are used by trained dental personnel in dental practices and laboratories. The T1 Spray is intended to be used to clean and lubricate dental handpieces.
Light	No	No	Yes
Spray	No	No	No
Head height (mm)	11,4	11,4	12,2
Head diameter (mm)	8,7	8,7	8,7
Weight	70 g	98 g	66 g
Material	Stainless Steel	Stainless Steel	Titanium
Apex-Function	Apex Locator via SIROEndo	Apex Locator via SIROEndo and Root ZX	Apex Locator via SIROEndo

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Endodontic contra-angle handpieces	Dentsply (K103653)	W&H (K090931)	Morita (K031204)	Nouvag (K042822)
Product Designation	E3 Torque Control Motor	ENTRAN EB-300	DENTAPORT ZX	TCM Endo V
Operating Principle	straight and contra-angle handpiece	straight and contra-angle handpiece	straight and contra-angle handpiece	straight and contra-angle handpiece
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.	Modular electrical system for mechanical preparation of the root canal, using a special root canal instrument (>>ENDO file<<), which is intended by the manufacturer for use in the mechanical and rotary preparation of the root canal.	The DENTAPORT ZX is a dental root canal measurement and treatment device that can measure the length of the root canal and enlarge the canal while monitoring the position of the file tip inside the canal.	The TCM Endo V is a dental root canal measurement and treatment device that can measure the length of the root canal and enlarge the canal while monitoring the position of the file tip inside the canal.
Light	No	No	Yes	No
Spray	No	No	Yes	No
Head height (mm)	11,4	Miniature Head	12,5	Miniature Head
Head diameter (mm)	8,7	Miniature Head	n/a	Miniature Head
Weight	70 g	85	70	n.a
Material	Stainless Steel	Stainless Steel	Stainless Steel	n.a
Apex-Function	Apex Locator via Dental Treatment Unit or SIROEndo Pocket	No	Yes	Yes

7 NON CLINICAL TESTING

The Sirona Dental System T1 LINE Endo 6 L, ENDO 6:1 and SIRONiTi Apex contra-angle handpieces comply with the following performance standards:

- ISO 14457 First Edition 2012-09-15 Dentistry - Handpieces And Motors
- ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management system
- ISO 7405 Second Edition 2008-12-15 Dentistry - Evaluation Of Biocompatibility Of Medical Devices Used In Dentistry [Including: Amendment 1 (2013)]
- ISO 14971 Second Edition 2007-03-01 Medical Devices - Application Of Risk Management To Medical Devices
- ISO 15223-1 Second Edition 2012-07-01 Medical Devices - Symbols To Be Used With Medical Device Labels, Labeling, And Information To Be Supplied - Part 1: General Requirements
- AAMI ANSI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013 Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care Facilities
- DIN EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- EN ISO 13485:2003 – Medical devices – Quality management systems -- Requirements for regulatory purposes
- DIN EN ISO 17664:2004 – Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
- DIN EN ISO 21531:2009 – Dentistry -- Graphical symbols for dental instruments
- ISO 3964 : 1982 - Dental handpieces – Coupling dimensions

An evaluation using relevant literature and a critical appraisal of the handpieces by a medical professional have been performed.

8 CONCLUSION

Based on a comparison of intended use, indications, principal of operations, features and technical data, the Sirona Dental Systems T1 LINE ENDO 6 L, ENDO 6:1 and SIRONiTi APEX are similar in design and function to the Predicate Devices. Therefore, the subject device is substantially equivalent to the predicate device.