K131319

MAY 30 2014

510(k) Summary

for

Sirona Dental Systems T1 / T2 / T3 Turbine family

with serial no. > 600 000

1 Sponsor

Sirona Dental Systems GmbH
Fabrikstrasse 31
D-64625 Bensheim
Germany

Contact Person: Fritz Kolle
Telephone: 49 6251 16 32 94

Date Prepared: May 1, 2013

2 Device Name

Proprietary Name: T1 / T2 / T3 Turbine family with serial no. > 600 000

Common/Usual Name: High speed air turbine

Classification Name: Handpiece, air-powered, dental

3 Predicate Devices

Nakanishi Ti-Max X Turbine (K113655) and the Morita Twin Power Turbine (K 043498)

4 Intended Use

The turbines of the T1 / T2 / T3 Turbine family are intended for the

- Preparation of cavities and crowns
- Removal of carious material
- Removal of fillings
- Processing of tooth and restoration surfaces
- Reducing hard tooth structure

4.1 Device Description

The Sirona Dental Systems T1 / T2 / T3 turbine family consists of air powered, high speed handpieces. The handpieces are reusable, ergonomically shaped and include (T1 and T2 Turbines) a fiber optic light system. The water delivery geometry includes 4 pair of water / air spray nozzles just below the head with one way retraction valves to prevent the ingress of external water or air, when the spray system is shut down. The devices are sterilizable in an autoclave. The turbines are provided in three variants: **control, boost and mini.**

In addition, the turbines are compatible with the following quick-coupling:

- Sirona R coupling
- Sirona F coupling
- Sirona B coupling
- KaVo coupling
- W&H coupling
- NSK MachLite coupling
- NSK QD-J coupling

5 Summary of the technological characteristics

The Sirona Dental Systems T1 / T2 / T3 turbine family is similar in the operating principle, technical data and performance to other high speed dental handpieces currently in the US commercial distribution. Examples of substantially equivalent devices include Nakanishi Ti-Max X Turbine (K113655) and the Morita Twin Power Turbine (K 043498). Below is a comparison of the proposed device to the predicate devices.

Table 1: Comparison of the proposed device to the declared predicate devices.

	Sirona T1 / T2 / T3 turbine family	Nakanishi Ti-Max X (K113655)	Morita Twin Power (K043498)
Principle of operation	Turbine Air driven [1]	Turbine Air driven	Turbine Air driven
Couplings to treatment chair	Sirona, Kavo, NSK, W&H	Sirona, Kavo, NSK, W&H, Bienair	Sirona, Kavo, NSK, W&H, Morita
Speed range	250000-400000	300000-450000	320000-400000
Power [W]	22/ 23/ 20	16-22	18 -22
Chuck	Push button FG	Push button FG	Push button FG
Light intensity [lux]	25000	Data not available	25000
Intended use	- Preparation of cavities and crowns - Removal of carious material - Removal of fillings - Processing of tooth and restoration surfaces - Reducing hard tooth structure	... intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations and restorations and polishing teeth.	TWIN POWER TUBINE is for use by authorized persons in the practice of the dentistry

1 As described in Sec. 11.1 ion page 9 and 10 in the original submission

6 Performance Testing

The Sirona T1 / T2 /T3 turbine family complies with ISO 14457 Dentistry — Handpieces and motors, ISO 1797 Dental Rotary Instruments – Shanks, ISO 9168 Dental Handpieces – Hose Connections, ISO 21531 Dentistry — Graphical symbols for dental instruments, additional performance testing was conducted to validate the sterilization process, device effectiveness and biocompatibility. Reverse engineering of the quick coupling was also conducted.

7 Clinical Testing

Clinical testing has not been performed.

8 Conclusion

Based on a comparison of intended use, indications, principal of operations, features and technical data, the Sirona Dental T1 / T2 / T3 high speed turbine family is substantially equivalent to its Predicate Devices.

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

May 30, 2014

Sirona Dental Systems GmbH
Mr. Fritz Kolle
Regulatory Manager
Fabrikstrasse 31
Bensheim, Germany D-64625

Re: K131319
Trade/Device Name: T1/T2/T3 Turbine family with serial n. > 600,000
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: April 25, 2014
Received: April 28, 2014

Dear Mr. Kolle:

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 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" (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,

Mary S. Runner -S

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

4 INDICATIONS FOR USE STATEMENT

Indications for use

510(k) Number (if known): K131319

Device Name: T1 / T2 / T3 Turbine family with serial n. > 600 000,
Models:

T1 CONTROL S ;T1 CONTROL K; T1 CONTROL W; T1 CONTROL N; T1 Boost S; T1 Boost K; T1 Boost W; T1 Boost N; T1 mini S; T1 mini K; T1 mini W; T1 mini N; T2 CONTROL S; T2 CONTROL K; T2 CONTROL W; T2 CONTROL N; T2 Boost S; T2 Boost K; T2 Boost W; T2 Boost N; T2 mini S; T2 mini K; T2 mini W; T2 mini N; T3 Boost S; T3 Boost K; T3 Boost W; T3 Boost NQ; T3 mini S; T3 mini K; T3 mini W; T3 mini NQ;

Indications for Use:

The turbines of the T1 / T2 / T3 Turbine family are intended for the
- Preparation of cavities and crowns
- Removal of carious material
- Removal of fillings
- Processing of tooth and restoration surfaces
- Reducing hard tooth structure

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

Andrew I. Steen -S
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Concurrence of CDRH, Office of Device Evaluation (ODE)
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