



Food and Drug Administration
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December 8, 2015

Codent Technical Industry Co., Ltd.
Chin-Ting Wen
Specialist
5f. No.90, Luke 5th Rd., Luzhu District
Kaohsiung City, 82151
TAIWAN

Re: K152146

Trade/Device Name: High Speed Handpieces and Accessories

Regulation Number: 21 CFR 872.4200

Regulation Name: Dental Handpiece and Accessories

Regulatory Class: I

Product Code: EFB

Dated: September 7, 2015

Received: September 9, 2015

Dear Chin-Ting Wen:

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" (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 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) Summary

6-1 Submission Date:

July 31, 2015.

6-2 Type of 510(k) Submission:

Traditional 510(k)

6-3 Submitter Address and Registration:

Manufacturer:	Codent Technical Industry Co., Ltd
Address:	5F., No.90, Luke 5th Rd., Luzhu Dist., Kaohsiung City 821, Southern Taiwan Science Park, Taiwan
Phone:	+886-7-695-5533 ext.812
Fax:	+886-7-695-5683
Contact:	Chin-Ting Wen / Specialist
Establishment Registration Number: 3004082152	

6-4 Identification of the Device:

Device Trade Name	High Speed Handpieces and Accessories
Common Name:	Handpiece, Air-Powered, Dental
Classification Name	Dental Handpiece & Accessories
Device Classification	1
Regulation Number	872.4200
Panel	Dental
Product Code	EFB

6-5 Predicate Device Information:

Primary Predicate

Predicate Device Name:	CODENT DENTAL AIR-POWERED HANDPIECE, MODEL HPS
Manufacturer:	Codent Technical Industry Co., Ltd.
Product Code:	EFB
510(k) Number:	K033213
Concurrence date	February, 06, 2004

Reference Predicate

Predicate Device Name:	430 SWL 45 AND 430 SW 45 HIGH-SPEED HANDPIECES
Manufacturer:	DENTALEZ GROUP, STARDENTAL DIVISION
Product Code:	EFB
510(k) Number:	K130455
Concurrence date	September, 25, 2013

Reference Predicate

Predicate Device Name:	W&H ROTO QUICK COUPLING
Manufacturer:	A-DEC, INC.
Product Code:	EFB
510(k) Number:	K945734
Concurrence date	October, 05, 1995

Reference Predicate

Predicate Device Name:	TIGER 500 SERIES HIGH SPEED HANDPIECES AND ATTACHMENTS
Manufacturer:	THUNDER TIGER CORP.
Product Code:	EFB
510(k) Number:	K102517
Concurrence date	April, 27, 2011

6-6 Intended Use and Indications for Use of the Subject Device:

High Speed Handpieces and Accessories are intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

6-7 Device Description:

High Speed Handpieces and Accessories include 45° High Speed Handpieces, 90° High Speed Handpieces and Couplings. The device description of High Speed Dental Handpieces and Accessories are as follows.

The models of 45° High Speed Handpieces are A45series (A45L, A45, A45M4) and 90° High Speed Handpieces are A6series (A6KL, A6K, A6L, A6, A6M4, A6B2), A5series (A5KL, A5K, A5L, A5, A5M4, A5B2), A4series (A4, A4M4, A4B2), A3series (A3, A3M4, A3B2), E-6510series (E-6510K, E-6510N), E-6500series (E-6500K, E-6500N), E-6110series (E-6110K, E-6110N), E-6100series (E-6100K, E-6100N), HPXseries (HPX4CML-Ti, HPX4CQ, HPX4CQ-Ti), HPMseries (HPM1CML, HPM1CQ, HPM1C4, HPM1C2, HPM1S4, HPM1S2) and HPKseries (HPK1C4, HPK1C2, HPK1S4, HPK1S2). And the accessories of High Speed Handpiece are Couplings, the models of Accessories are

Q6series (Q6M, Q6M-LED, Q6K, Q6K-LED, Q6KW), Q5series (Q5K), Q4series (Q4K, Q4M, Q4Q), Q2series (Q2Q), CKseries (CK4010, CK4000) and CNseries (CN4010, CN4000)

Concerning the head of handpiece and angle of shaft, the handpiece could be 45° or 90° . In general, dentist usually uses 90° handpiece having teeth treatment. Except for wisdom teeth, 45° handpiece is considered more desirable for wisdom teeth operation. It is because the 45° angle is more appropriate for the angle of eruption of wisdom teeth. Coupling is the accessory for handpiece to connect with tubes of dental unit. It could be divided into four types. There are 2-hole coupling (drive air and spray water holes), 4-hole coupling (drive air, exhaust air, spray air and spray water holes), 5-hole coupling (drive air, exhaust air, spray air and spray water and fibre optic holes) and 6-hole coupling (drive air, exhaust air, spray air, spray water and two of electrical contacts holes). The use of the coupling of handpiece is due to the number of tubes of dental unit.

- Cooling system includes single, triple and quattro spray.
- Head size of high speed handpiece has standard, miniature and torque head.
- 45° High Speed Handpieces are able to run 360,000 rpm±10% and 90° High Speed
- Handpieces are able to run 400,000 rpm±10%.
- A45L, A6KL, A5KL, A6L, A5L, E-6510K, E-6510N, E-6110K, E-6110N, HPX4CML-Ti and HPM1CML have light function.
- Q2Q and Q4Q assemble with A6, A5, A4, A3, A45, HPX4CQ, HPS3CQ, HPS1CQ, HPM1CQ and HPX4CQ-Ti. Q5K, Q6K, Q6K-LED and Q6KW assemble with A6KL, A6K, A5KL and A5K. Q6M and Q6M-LED assemble with A6L, A5L, A45L, HPX4CML-Ti, HPS3CML and HPM1CML. Q4M assembles with HPS3CM. Q4K assembles with A6K and A5K. CK-4010 assembles with E-6510K and E-6110K. CK-4000 assembles with E-6500K and E-6100K. CN-4010 assembles with E-6510N and E-6110N. CN-4000 assembles with E-6500N and E-6100N.

6-8 Substantial Equivalent Devices :

The High Speed Handpieces and Accessories submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the devices cleared in K033213, K013455, K945764 and K102517. In the chart below, the entire intended use for all predicate devices is listed, but it should be noted that the proposed device has SE with CODENT DENTAL AIR-POWERED HANDPIECE, MODEL HPS and 430 SWL 45 AND 430 SW 45 HIGH-SPEED HANDPIECES, W&H ROTO QUICK COUPLING and TIGER 500 SERIES HIGH SPEED HANDPIECES

AND ATTACHMENTS.

Differences between the devices cited in this section do not raise any new questions of safety or effectiveness.

Comparison of Technical Features

Item	Proposed Device	Primary Predicate Device (K033213)	Reference Predicate Device (K130455)	Reference Predicate Device (K945734)	Reference Predicate Device (K102517)
Similarity					
Classification	Class I	Class I	Class I	Class I	Class I
Code or Federal Regulations	872.4200	872.4200	872.4200	872.4200	872.4200
Product Code	EFB	EFB	EFB	EFB	EFB
Over-the-counter Medical Device	No	No	No	No	No
Device design					
Operational modes	Air-powered	Air-powered	Air-powered	Air-powered	Air-powered
Water spray	Single/Triple /	Single/Triple	Single	N/A	N/A
Coupling pin	2-pin/4-pin/5-pin/	2-pin/4-pin/6-pin	4-pin/6-pin	2-pin/4-pin/6-pin	5-pin
Fiber optics	With light/ Without light	With light/ Without light	With light/ Without light	With light/ Without light	With light
Dimensions(mm)	Length: 84~117 Width: 19~21	Length: 84~117 Width: 19~21	unknown	N/A	N/A
Accessories	with coupling/ without coupling	with coupling/ without coupling	with coupling	N/A	N/A
Composition of main materials	Stainless steel, Brass, Aluminum, Titanium	Stainless steel, Brass, Aluminum, Titanium	unknown	unknown	unknown
Technical specifications					
Chunk design	Push Button	Push Button	Push Button Chuck	N/A	N/A
Light intensity	25,000 lux to 32,000	25,000 lux to 32,000	unknown	N/A	N/A
Bur extraction force	22N~45N	22N~45N	22N~45N	N/A	N/A
Maximum air/water pressure	air: 1.5 l/min at 200kPa (2bar) water: 50ml/min	air: 1.5 l/min at 200kPa (2bar) water: 50ml/min	air: 1.5 l/min at 200kPa (2bar) water: 50ml/min	N/A	N/A
Speed in rpms	350,000 rpm to 400,000rpm	350,000 rpm to 380,000rpm	400,000rpm	N/A	N/A

Intended Use	
Proposed Device	High Speed Handpieces and Accessories are intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.
Primary Predicate Device (K033213)	Codent Dental Air-Powered Handpiece, model HPS is intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations and restorations and polishing teeth.
Reference Predicate Device (K130455)	The 430 SWL 45 High-Speed Handpiece is a fiber optic, swivel connector type handpiece with a lubefree, ceramic bearing, and push button autochuck turbine. The 430 SW 45 High-Speed Handpiece is a non-fiber optic version of the 430 SWL 45 Handpiece.
Reference Predicate Device (K945734)	Unknown
Reference Predicate Device (K102517)	Tiger 500 Series High Speed Handpieces are intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations and restorations and polishing teeth.
Models	
Proposed Device	<p><u>High Speed Handpiece</u></p> <ul style="list-style-type: none"> - <u>A45series:</u> A45L, A45, A45M4 - <u>A6series:</u> A6KL, A6K, A6L, A6, A6M4, A6B2 - <u>A5series:</u> A5KL, A5K, A5L, A5, A5M4, A5B2 - <u>A4series:</u> A4, A4M4, A4B2 - <u>A3series:</u> A3, A3M4, A3B2 - <u>E-6510series:</u> E-6510K, E-6510N - <u>E-6500series:</u> E-6500K, E-6500N - <u>E-6110series:</u> E-6110K, E-6110N - <u>E-6100series:</u> E-6100K, E-6100N - <u>HPXseries:</u> HPX4CML-Ti, HPX4CQ, HPX4CQ-Ti - <u>HPMseries:</u> HPM1CML, HPM1CQ, HPM1C4, HPM1C2,

	<p>HPM1S4, HPM1S2</p> <p>- <u>HPKseries</u>: HPK1C4, HPK1C2, HPK1S4, HPK1S2</p> <p><u>Accessories</u></p> <p>- <u>Q6series</u>: Q6M, Q6M-LED, Q6K, Q6K-LED, Q6KW</p> <p>- <u>Q5series</u>: Q5K</p> <p>- <u>Q4series</u>: Q4K, Q4M, Q4Q</p> <p>- <u>Q2series</u>: Q2Q</p> <p>- <u>CKseries</u>: CK4010, CK4000</p> <p>- <u>CNseries</u>: CN4010, CN4000</p>
Predicate Device (K033213)	HPS3CML, HPS3CQ, HPS1CQ, HPS3C4, HPS3CM and HPS3C2.
Reference Predicate Device (K130455)	430 SWL 45 and 430 SW 45.
Reference Predicate Device (K945734)	RQ03, RQ04, RQ24 and RQ34
Reference Predicate Device (K102517)	QC5015K
Standards	
Proposed Device	ISO 14971:2007, ISO 9168:2009, ANSI/AAMI ST79:2010/A3:2012, ISO 14457:2012, ISO 10993-1:2009.
Primary Predicate Device (K033213)	ISO 7785-1:1997 , ISO 13294:1997, ISO, ISO 9168:2009, ISO 14971:2007, ANSI/AAMI ST79:2010/A3:2012, ISO 14457:2012, ISO 10993-1:2009.
Reference Predicate Device (K130455)	ISO 7785-1:1997, ANSI/AAMI ST79:2010 & A1:2010 & A2:2011, AAMI/ANSI/ISO 14937:2009 and ISO 14971:2009.
Reference Predicate Device (K945734)	Unknown
Reference Predicate Device (K102517)	ISO 7785-1:1997

The Standards of ISO 7785-1:1997 and ISO 13294:1997 that K033213, K130455 and K102517 used are canceled and replaced by ISO 14457:2012 according to the ISO 14457:2012.

6-9 Non-clinical Testing:

The tests listed below were conducted for High Speed Handpieces and Accessories in accordance with the following standards.

- ISO 14971:2007 Medical devices - Application of risk management to medical devices
- ISO 9168:2009 Dentistry - Hose connectors for air driven dental handpieces
- ANSI/AAMI ST79:2010/A3:2012 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities, Amendment 3
- AAMI/ANSI/ISO 17665-1:2006/(R)2013 – Sterilization of health care products – moist heat – part 1: requirements for the development, validation, and routine control of a sterilization process for medical devices.
- ISO 11138-3:2006 – Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat
- ISO 14457:2012 Dentistry - Handpieces and Motors
- ISO 10993-1:2009 – Biological Evaluation of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process
- ISO 10993-5:2009 – Biological evaluation of medical devices – tests for in vitro cytotoxicity
- ISO 10993-10:2010 – Biological evaluation of medical devices – tests for intracutaneous irritation and skin sensitization
- Guidance for Industry and FDA Staff-Dental Handpieces-Premarket Notification[510(k)] Submissions

All the test results demonstrate the performance of High Speed Handpieces and Accessories meets the requirements of its pre-defined acceptance criteria and intended uses. Differences in device design, such as type of water spray, small dimensional differences for head and/or length, maximum rpm, have no impact on the usability and function of the proposed devices. Conformity with the above standards also demonstrates that the High Speed Handpieces and Accessories are substantially equivalent to the predicate devices.

6-10 Conclusion:

After analyzing bench testing data, and considering conformance to consensus standards recognized by FDA in terms of risk, connectors, sterilization, biocompatibility, and FDA guidance, it can be concluded that High Speed Handpieces and Accessories is substantially equivalent to the predicate devices.