SECTION E. 510(K) SUMMARY

K071632

OCT 18 2007

coltène whaledent

Owner and Contact	**Device Owner and Manufacturer:** Coltene/Whaledent, Inc. 235 Ascot Parkway Cuyahoga Falls, Ohio 44223-3701 Ph. 330-916-8800 Fax 330-916-7089 **Registration Number:** 2416455 **Contact Person:** Glenn Persello 235 Ascot Parkway Cuyahoga Falls, Ohio 44223 Ph. 330-916-8837 Summary prepared on June 6, 2007
Device	Trade name – PerFect® Tissue Contouring System II (PerFect® TCS II) Common name – Electrosurgical Dental Unit Panel Part 872 – Dental Devices Subpart E – Surgical Devices Sec. 872.4920 – Unit, Electrosurgical and Accessories, Dental Product Code - EKZ Classification – Class II
Predicate Device	The Strobex Ultron Electrosurge Unit that is legally marketed under 510(k) K850666.
Intended Use	The PerFect® TCS II is intended only for use by licensed dental practitioners who have received appropriate training in the application of electrosurgery. This device is intended to cut or remove soft tissue or to control bleeding during dental and periodontal surgical procedures in the oral cavity.
Technological Characteristics	See table below See Section 12. Substantial Equivalence for additional information.

Characteristic	Strobex Electrosurge	PerFect® TCS II
Intended Use	Same	Same
Indications for use	Same	Same
Electrodes	Same	Same
Software / Firmware	None	None

SECTION E. 510(K) SUMMARY

General Description	PerFect® TCS II is an electrosurge unit designed to appeal to both the new and experienced user of electrosurgery. PerFect® TCS II can simplify and enhance the results of a variety of everyday procedures performed by virtually every dentist, including the control of bleeding, gaining access to caries and aesthetic contouring of gingiva. The PerFect® TCS II is an AC-powered device consisting of a controlled power source and a set of cutting and coagulating electrodes. The radio-frequency energy used by PerFect® TCS II is able to sever and coagulate tissue because it focuses the heat energy at the small, active electrode. While the active electrode remains cold, sufficient heat energy is generated in its path to sever and coagulate effectively. The high-frequency energy focused at the active electrode returns to the electrosurge through the large dispersive electrode, which is placed on the back of the dental chair against the patient's back during use. The PerFect® TCS II has two output modes: "Cut'' and "Coag.'' The operator can adjust the intensity of these modes. When the power output is adjusted properly, the electrode cuts without resistance, permitting an extraordinary degree of control and precision. The PerFect® TCS II is designed to use the Strobex (predicate) handpiece electrodes. These handpiece electrodes have not changed in biocompatibility materials (stainless steel) or in the manufacturing process. In addition performance testing was conducted by UL that included functional testing of electrodes sterilized twenty times via the recommended cycle.
Performance Testing	The PerFect® Tissue Contouring System II (PerFect® TCS II) complies with IEC 60601-1:1988 + A1: 1991 + A2: 1995, IEC 60601-2-2, EN55011, Group1, EN60601-1-2 and EN60601-2-2 Clause 36. The product was investigated to the following additional standards: EN 60601-1: 1990 + A1:1993 + A2:1995 + A13:1996, CAN/CSA C22.2 No. 601.1-M90 (R1997), CAN/CSA C22.2 No. 601.1S1-94, and CAN/CSA C22.2 No. 601.1B-90. The PerFect® TCS II complies with the following National Differences: AT, AU, BE, CA, CH, CZ, DE, DK, FI, FR, GB, GR, HU, IE, IT, NL, NO, PL, PT, SE, SI, SK, TR, US. PerFect® TCS II was tested by Underwriters Laboratories Inc. Melville Division 1285 Walt Whitman Road Melville, NY 11747-3081 USA.
Performance Testing Conclusions	The PerFect® TCS II has demonstrated that it is equally effective as the predicate device and is in fact a safer device due to the fact it has been certified to comply to the requirements of the recognized standards by performance testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2007

Mr. Glenn Persello
Compliance Engineer
Coltène Whaledent, Incorporated
235 Ascot Parkway
Cuyahoga Falls, Ohio 44223-3701

Re: K071632
Trade/Device Name: PerFect® Tissue Contouring System II (PerFect® TCS II)
Regulation Number: 872.4920
Regulation Name: Dental Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: EKZ
Dated: September 12, 2007
Received: September 13, 2007

Dear Mr. Persello:

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.

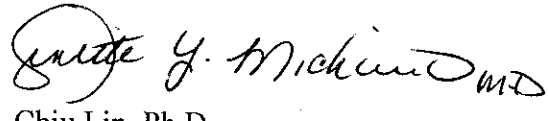
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION D. INDICATIONS FOR USE STATEMENT

coltène whaledent

Indications for Use

510(k) Number (if known): K071632

Device Name: PerFect® Tissue Contouring System II (PerFect® TCS II)

Indications for Use:

The PerFect® TCS II is intended to cut or remove soft tissue or to control bleeding during dental and periodontal surgical procedures in the oral cavity.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

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

510(k) Number: K071632