

NOV - 5 1999

510(K) SUMMARY

K990546

Applicant's Name & Street Address

Green River Inc. dba Summit Dental Systems (SDS)
5101 NW 21st Avenue , suite 141
Fort Lauderdale, Fl. 33309

Contact Person: Cesar R. Coral, President
Telephone and Fax Numbers of Applicant or Contact: (954) 733-4300
(954) 733-4303

Address(es) of Manufacturing and Sterilizing Site(s):

DELIDENT LTD.
19 Keren Kayemet Street
Petach Tikva 49372
Israel

Trade Name: Delsonic 2000 Ultrasonic Scaler

Common Name: Ultrasonic Scaler

Classification Name : Scaler, Ultrasonic (No.8724850, Code 76ELC, Class II)

Substantial Equivalence Comparison:

- Dentisply

Description of Device:

The DELSONIC 2000 is an automatically tuned piezo ultrasonic scaler that generates linear tip movement at 29kHz for efficient, yet gentle calculus removal. The DELSONIC piezo ultrasonic scaler is designed for the prevention of cross-infection with fully autoclavable handpiece sleeves sterilisable removable control knobs and wipe clean display panel

Intended Use of Device:

The DELSONIC 2000 Ultrasonic Scaler is intended to be used fast and reliable removal of light to heavy calculus and plaque. This 29kHz ultrasonic system provides automatic tuning for each scaling insert.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Veronica Coral
Vice President
Green River, Incorporated
5101 N.W. 21st Avenue, Suite 141
Fort Lauderdale, Florida 33309

Re: K990546
Trade Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: February 19, 1999
Received: February 22, 1999

Dear Ms. Coral:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

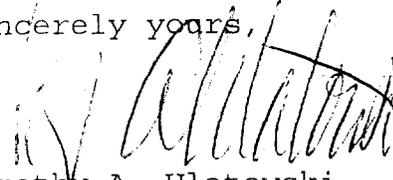
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 990546/1A1

Page 1 of 1
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510(k) NUMBER (IF KNOWN): K 990546

DEVICE NAME: Delsonic 2000

INDICATIONS FOR USE:

The delsonic 2000 Ultrasonic Scaler is intended to be used for fast and reliable removal of light to heavy calculus and plaque. This 29KHZ ultrasonic system provides automatic tuning for each scaling insert.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)

SK
12

Susan Ramo

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990546