

ATE 11 199

GREEN RIVER INC.

K990545

IMPORTERS AND EXPORTERS

101 N.W. 21ST. AVE. SUITE 141 FORT LAUDERDALE, FL 33309 (954) 733-4300 TLX. 332311 GRILDC FAX: (954) 733-4303

510(K) SUMMARY**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):

DELDENT LTD.
 19 Keren Kayemet Street
 Petach Tikva 49372
 Israel

Trade Name: Jetsonic 2000 Ultrasonic Scaler and Air Polishing Unit**Common Name: Ultrasonic Scaler/Air Polisher**

Classification Name : Scaler, Ultrasonic (Code 76ELC, Class II) Jet Polisher
 Code 76KOJ, Class III

Substantial Equivalence Comparison:

- Dentsply

Description of Device:

Jetsonic 2000 combines both ultrasonic scalling and air polishing functions in one compact unt that answers all prophylaxis needs.

Intended Use of Device:

The Jetsonic 2000 combination unit (ultrasonic scaler and air polisher) provides answers to all prophylaxis needs. The air polishing function is intended to be used to remove stubborn stains, plaque and soft debris. The scaler functions is intended to be used for cauculus removal.

Device applications: routine oral prophylaxis, routine polishing, especially in hard to reach fissures and interproximal areas, prior to enamel etching and bonding techniques and prior to bonding orthodontic bands and brackets.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 11 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Cesar R. Coral
President
Green River, Incorporated
5101 N.W. 21st, Avenue
Suite 141
Fort Lauderdale, Florida 33309

Re: K990545
Trade Name: Jetsonic 2000
Regulatory Class: III
Product Code: KOJ
Dated: May 18, 1999
Received: May 20, 1999

Dear Mr. Coral:

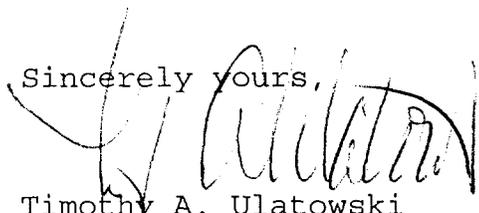
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 pre-market 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.

Page 2 - Mr. Coral

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

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K 990545
Device Name: **JETSONIC 2000 ULTRASONIC SCALER AND AIRPOLISHING UNIT**

This unit combines both ultrasonic scaling and airpolishing functions in one compact unit that answers all prophylaxis needs. The air polishing function is intended to be used to remove stubborn stains, plaque and soft debris. The scaler functions is intended to be used for calculus removal. Device applications: Routine oral prophylaxis, routine polishing especially in hard to reach fissures and interproximal areas, prior to enamel etching and bonding techniques and prior to bonding orthodontic bands and brackets.
PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDH, office of Device Evaluation

Prescription Use or Over-the-Counter Use

(Per 21CFR 801.109)

Susan Brown

(optional format 1-2-96)

(Division Sign-Off)
Division of **Dental, Infection Control,**
and General **Hospital Devices**
510(k) Number K990545