DEC - 4 2000

510(k) Summary

K002753

Submitted By:
Spartan Marketing Group
1663 Fenton Business Park Ct.
Fenton, MO 63026
USA

Establishment Registration Number - #1926480

Telephone Number – 636.343.8733
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Contact Person: Aldo Eagle
Title: Vice President

Date of Application – July 20, 2000

Device Name:

- Proprietary Name- Spartan A-10
- Common Name- Ultrasonic Scaler
- Proposed Classification- Ultrasonic Scaler

- Class II
- Product Code- ELC

Predicate Device- Substantial Equivalence
The Spartan MTS is substantially equivalent in terms of safety and effectiveness to the marketed ultrasonic scalers , (K961158) Suprasson P5 Booster and (K953026) miniPiezon.

Device Description
The Spartan A-10 is an Ultrasonic Scaler with a detachable handpiece. The handpiece accepts several different types of tips for periodontic and endodontic use. These characteristics are the same or similar for the "miniPiezon" by EMS, K953026 and Suprasson P5 Booster, K961158, by Satelec.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2000

Mr. Aldo E. Eagle
Vice President
Spartan Ultrasonics, Incorporated
1663 Fenton Business Park Court
Fenton, Missouri 63026

Re: K002753
Trade Name: Spartan A-10
Regulatory Class: II
Product Code: ELC
Dated: July 20, 2000
Received: September 5, 2000

Dear Mr. Eagle:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Patricia Cuerda /for

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

Enclosure

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510(k) NUMBER (IF KNOWN): K002753

DEVICE NAME: Spartan A10

INDICATIONS FOR USE:

This ultrasonic scaler is used for periodontic, hygiene and endodontic procedures. Ultrasonics should be used for root planing, removal of blockages from a root canal and for general scaling of teeth

(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)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K002753

DE II