AUG 25 1999 K991885

510(k) Summary

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

Establishment Registration Number - #1926480

Telephone Number - 314.343.8733
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Contact Person: Aldo Eagle
Title: Director of International Business Development

Date of Application – May 28, 1999

Device Name:

- Proprietary Name - Minijet Syringe
- Common Name - Cartridge Syringe or Intraligamental Syringe
- Proposed Classification Name - Syringe, Cartridge

- Class II
- Product Code - 76 E J I

Predicate Device – Substantial Equivalence

The Minijet Syringe is substantially equivalent in terms of safety and effectiveness to the marketed injection devices of (K823536) Intralig and (K802483) Ligmaject

Device Description

The Minijet Syringe is a cartridge syringe with a metal syringe barrel to which the metal or plastic hub of the injection needle is threaded. The barrel accommodates a 1.8cc anesthetic cartridge. The syringe has a plunger on one end, which engages the rubber piston of the anesthetic cartridge. These characteristics are the same or similar for the "Intralig", by Miltex, (K823536) and Ligmaject, (K802483).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 1999

Mr. Aldo Eagle
Director
Spartan Ultrasonics, Incorporated
1663 Fenton Business Park Court
Fenton, Missouri 63026

Re: K991888
Trade Name: Miniject
Regulatory Class: II
Product Code: EJI
Dated: May 28, 1999
Received: June 2, 1999

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 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

K991888/A1

Obtura Spartan
"Enhancing Endodontic Success"

510(k) Number (if known): K991888

Device Name: MINIJECT

Indications For Use:

This product is intended to be used to administer intraligamental injections of anaesthetic product, through a two-ended needle.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991888

Prescription Use ✓ OR Over-The-Counter Us
(Per 21 CFR 801.109)

(Optional Form

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