JAN 18 2000

Summary of Safety and Effectiveness Information Section 510(k) Premarket Notification	LiteSaber™ 2000 Laser Handpiece

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

K993942

1. ***Device Name:***

Device Trade Name: LiteSaber™ 2000
Common Name: Laser accessory
Classification Name: Laser Instrument, Surgical, Powered

2. ***Establishment Name & Registration Number:***

Name: Laser Dental Innovations, Inc.
Number: Pending

3. ***Classification:***

§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.
§ 874.4500 Laser, ENT
§ 874.4490 Laser, Otolarngology
§ 884.4550 Laser, Surgical, Gynecological

Device Class: Class II
Classification Panel: General and Plastic Surgery, OB/GYN, ENT, Dermatology Device Panels
Product Code(s): 79GEX, 77EWG, 77LMS, 85HHR respectively

4. ***Equivalent / Comparison Device:***

1. **Novatip Family of Laser Handplece Tips, K971539** by Xanova Corp.

The LiteSaber™ 2000 tips function in the same way as the Novatip Laser Handpiece Tips. The LiteSaber™ 2000 operates with the same size fibers, and does not affect the spot size or the function of the laser beam. The materials used to construct the LiteSaber™ 2000 are the same or are the functional equivalent of those used in the Novatip handpeice. The LiteSaber™ 2000 does not have a direct impact on the transmission of the laser energy because the handpiece includes no optics. The LiteSaber™ 2000 is used to grasp and direct the laser fiber in clinically useful ways. Thus, it is believed that the LiteSaber™ 2000 offers even less concern than the Novatip.

10. ***Device Description:***

Background: The LiteSaber™ 2000 is an "after-market" accessory for use with an existing surgical laser system. The device may be used as a complete system (handpiece and tips) or just the tips may be used with an existing handpiece of the ultradent style. The LiteSaber™ 2000 is used as a direct replacement for the laser handpiece supplied as original equipment or the original equipment laser handpiece tip. The LiteSaber™ 2000 is designed address the need to direct the beam in a direction other than straight through the handpiece. Further, it does so without the need for refractive or reflective contact tips. The LiteSaber™ 2000 gently and effectively clasps the clad fiber while bending the distal bare fiber into a smooth radius. Pre-curved disposable tips channel the fiber. Precurved tips are available. The directional tips may be rotated 360 degrees. This allows the laser fiber to be directed laterally, up, down or any angle or radius in between. The tips are disposable and the handpiece is reusable.

The *LiteSaber™ 2000* laser handpiece is intended for use in general surgery, plastic surgery, dermatologic surgery, orthopaedic surgery, intraoral, maxillo-facial or dental soft tissue surgery including the marginal and interdental gingiva. The handpiece is "universal" in nature and is intended to be used in place of the handpiece supplied or provided by the laser manufacturer. The *LiteSaber™ 2000* is designed to accommodate all clad laser fibers between 200 and 400 microns diameter.

Cleared Indications for Use. The *LiteSaber™ 2000* indications for use are for the cleared indications for the laser system to which it is attached. For example, dermatological, ENT, general surgery, GYN surgery, oral/dental, maxillofacial, orthopaedic and podiatric procedures for the incision, excision, ablation, vaporization and hemostasis of soft tissue.

5. Applicant / Sponsor Name / Address:

Laser Dental Innovations
745 Dubanski Drive
San Jose, CA 95123
408.227.4674

6. Company Contact:

Mr. Howard Feinberg
Laser Dental Innovations
745 Dubanski Drive
San Jose, CA 95123
408.227.4674

7. Submission Correspondent:

Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Ln., Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 vox - 925.356.2654 fax

8. Sterilization Information:

The laser handpiece may be sterilized and/or re-sterilized until replacement is needed. After cleaning and inspection, standard steam autoclave processing at 270 degrees F. for 30 minutes will produce a sterility assurance level (SAL) of 10^{-6}. The tips are disposable and may not be resterilized.

The handpiece assembly must be washed, cleaned and rinsed thoroughly before resterilization. Hospital grade soap/detergent & water followed by surface scrubbing are employed. Refer to cleaning and sterilization instructions supplied with the device. Thoroughly rinse the handpiece in clear running water. Sterilize un-assembled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2000

Mr. David Schlerf
Laser Dental Innovations
c/o Buckman Company, Inc.
200 Gregory Lane
Suite C-100
Pleasant Hill, California 94523-3389

Re: K993942
Trade Name: LiteSaber™ 2000
Regulatory Class: II
Product Code: GEX
Dated: October 11, 1999
Received: November 19, 1999

Dear Mr. Schlerf:

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 current Good Manufacturing Practice requirement, 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) 594-4595. 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,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: **K993942**

Device Name: ***LiteSaber™ 2000***

Indications for Use:

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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephen Rhodes

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993942

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)