

JUL 20 1999

K991464

**FISMA INC.,**  
**3959 West 1820 South**  
**Salt Lake City, Utah 84104**  
**(801) 972-0500**  
**(801) 972-4884 (fax)**  
**Tracy S. Best, Regulatory Manager**  
**Preparation Date: April 26, 1999**

---

**Summary of Safety and Effectiveness for the:**

**Trade Name:** Dental 200, Dental 300, Dental 400  
**Common Name:** Argon Laser System  
**Classification Name:** Laser, Instrument, Surgical, Powered - 79 GEX

---

**Legally Marketed Predicate Devices for Substantial Equivalence:**

- \* Arago II, Argon Laser by: Premier Laser Systems
- \* Elite Family of Lasers, KTP Green by: FISMA Inc.

**Rationale for SE:** The Dental 200, 300, & 400 Lasers and Delivery Devices share similar indications for use, and similar design features including; wavelengths, beam integrity, and cooling type. Control systems such as interlock devices, (safety systems) and displays are constantly monitored for user intervention. Functional features such as; delivery power, pulse rates, energy type, and spot sizes are also similar. See Attachment "A" Comparison Chart of Equivalence.

---

**Description of Submitted Device:**

The Dental 200, 300, & 400 Laser Systems are an instrument used in the application of Dentistry. With a level of output power of up to 10.0 Watts on some models, and the selectable blue or green wavelengths, additional indications for use are warranted. The use of these dental laser devices are supported by a line of FiberFlex™ Fibers in sizes of; 200, 300, 400, & 600 microns. Cannulas specifically designed for use in Dentistry and as companion to the bare fibers.

---

**Intended Use the Dental Lasers:**

Laser-assisted Bleaching/Whitening of the teeth, Curing of all light sensitive bonding materials, (i.e., pit and fissure sealants, composite restorations, endodontic composite cores, composite cements for porcelain facings and inlays, periodontal splint material, and prosthetic reline and repair material). Also, Illumination purposes for the adjunctive use in caries detection and endodontic orifice location.

---

**Technological Characteristics and Substantial Equivalence:**

The Dental 200, 300, & 400 primary energy output source is an Argon Ion laser head for delivery to the patient. The selectable laser wavelength colors of green (treat) and blue (cure). Refer to the Table of Substantial Equivalence showing the individual system settings for these three lasers. This system has similar timing features for interval, and duration. The Aiming Beam is a visible Red Diode @ 630-680nm.

The Arago II Laser (Premier Laser Systems) uses identical wavelengths as the primary source of energy for delivery to the patient. The Arago II Laser System delivers similar power, spot sizes and pulses of equivalent duration. Indications for use are equivalent. The Aiming Beam is also a visible Red Diode.

The Elite Family Lasers are a diode-pumped system which delivers 532 nm laser light. These use a diode as the primary source of energy which is then converted to visible green 532 nm for delivery to the patient and treatment. The system delivers similar average power, durations and intervals. Although the wavelength is different, the final treatment results to the patient is identical. The Aiming Beam is a visible Red Diode @630-680nm.

**Conclusion:**

The Dental Laser Systems are substantially equivalent to other existing surgical laser systems in commercial distribution. Therefore a finding of substantial equivalence is requested for this submission.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 20 1999

Mr. Tracy S. Best  
Regulatory Manager  
FISMA, Inc.  
3959 West 1820 South  
Salt Lake City, Utah 84104

Re: K991464  
Trade Name: Dental 200, Dental 300, Dental 400  
Regulatory Class: GEX  
Product Code: II  
Dated: April 26, 1999  
Received: April 27, 1999

Dear Mr. Best:

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.

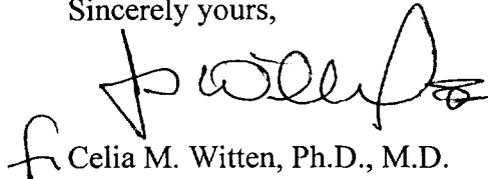
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Mr. Tracy S. Best

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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K991464

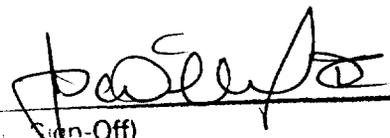
Device Name: Dental 200, Dental 300, Dental 400

Indications For Use:

- √ Laser-assisted Bleaching/Whitening of the teeth.
- √ Illumination purposes for the adjunctive use in caries detection and endodontic orifice location.
- √ Curing of all light sensitive bonding materials including:  
Pit and fissure sealants, composite restorations, endodontic composite cores, composite cements for porcelain facings and inlays, periodontal splint material, and prosthetic reline and repair material.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Device Sign-Off)  
Device Name: General Restorative Devices  
510(k) Number: K991464

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_