

XII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

(Separate Page)

A. Submitter: Alan A. Creamer, President, ICS of North American, Inc., 10054 Mesa Ridge Ct. San Diego, CA 92121

I. Classification: Class II.

II. Common or usual name: Argon Laser system

III. Proprietary Name: CYBER-LASE 2000™

IV. Registration No.: 61073

V. Classification Name: Argon laser system, powered, 79GEX, CFR 878.4810, Class II.

VI. Performance standards: None established (as a medical device) under section 514. Meets Performance Standards for Light-Emitting Products, 21 CFR 1040.10 (Laser Products) and 21 CFR 1040.11(a) (Medical Laser Products).

VII. Description: The device is a standard air-cooled argon laser emitting energy at 457 and 502nm. Output energy is less than 450 mW. The delivery system is a fused silica fiber optic system with a stainless steel handpiece. The laser operates on any 120 volt, alternating current, 20 ampere circuit. The unit is about 16" by 10" by 6.7" in dimension and weighs 20 lbs.

VIII. Labels and Labeling: Labels and Instructions for Use are provided. Competitive labels and labeling are provided and the products are compared.

IX. Indications for Use: source of illumination for curing dental restorative materials, and for tooth whitening activities.

X. Substantial Equivalence: The CYBER-LASE 2000™ is substantially equivalent to lasers cleared by Premier Laser Systems, Inc., as the product, "Arago" under 510(k) K971118, and other Premier lasers including Argon Curing Laser cleared under K961682. It also is equivalent to similar lasers cleared by other laser companies such as LaserMed, Inc. (Accucure 1000, cleared under K970637) and American Medical laser.

The "510(k) Substantial Equivalence Decision-making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed.



JAN 12 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Alan A. Creamer
President
ICS of North America, Inc.
10054 Mesa Ridge Court
San Diego, California 92121

Re: K983654
Trade Name: Cyber-Lase 2000™
Regulatory Class: II
Product Code: GEX
Dated: October 16, 1998
Received: October 19, 1998

Dear Mr. Creamer:

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.

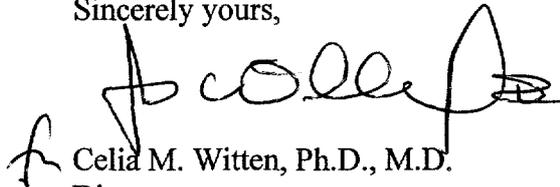
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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 'C. 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

IX. Indications for Use: [Separate Page]

K983654

510(k) Number: NA

Device Name: CYBER-LASE 2000™

This device is intended for use in:

1. Source of illumination for curing dental restorative materials,
2. Assisting in the whitening process in dental office.

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

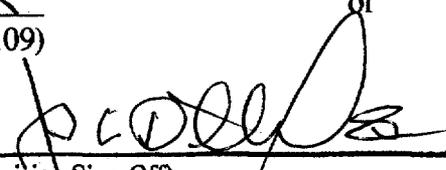
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

Over-The-Counter Use

(Optional Format 1-2-96)

or



(Division Sign-Off)

Division of General Restorative Devices 3

510(k) Number K983654