K033632

JAN 2 1 2004

Great Lakes Orthodontics, LTD.

An Employee Owned Company

Our Vision

"Delight our customers. Respect and help our co-workers."

510(k) SUMMARY

CONTACT PERSON: Mr. Mark Lauren Great Lakes Orthodontics 800-828-7626
mlauren@greatlakesortho.com

DATE PREPARED: November 10, 2003

TRADE OR PROPRIETARY NAME: Variflex™
COMMON NAME: Dental acrylic, heat-softening acrylic
CLASSIFICATION NAME: Denture relining, repairing or rebasing resin 872.3760
PRODUCT CODE: EBI

PREDICATE DEVICE: Clearsplint™ Astron Dental Corporation
815 Oakwood Road Unit G
Lake Zurich, IL 60047 800-323-4144

DEVICE DESCRIPTION
Variflex™ is a chemically cured soft dental acrylic. All components have been used in legally marketed devices or have been found to be safe for dental use.

INTENDED USE
Variflex™ is intended for the laboratory fabrication of dental appliances such as inter-occlusal splints and night guards.

TECHNOLOGICAL CHARACTERISTICS COMPARED WITH PREDICATE DEVICE
Variflex™ was evaluated as follows:

Mechanical properties, Hardness, Water absorption, Discoloration
Variation of physical properties with temperature

Variflex™ was also evaluated as follows:

MEM Elution Test	non-cytotoxic
Mucous membrane irritation	non-irritant
Kligman Maximization Test (NaCl)	non-sensitizer

We conclude that the similarity in composition between Variflex™ and the predicate device, as well as the performance data and biocompatibility results, supports the safety and effectiveness of Variflex™ for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 1 2004

Mr. Mark Lauren
Director of Research
Great Lakes Orthodontics, Ltd.
200 Cooper Avenue
Tonawanda, New York 14151-511

Re: K033632
Trade/Device Name: Variflex™ Heat Softening Acrylic
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: November 17, 2003
Received: December 01, 2003

Dear Mr. Lauren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. 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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033632

Great Lakes Orthodontics
200 Cooper Avenue
Tonawanda, NY 14150

Device Name: Variflex™ heat softening acrylic

Indications for Use:

Variflex™ is intended for the laboratory fabrication of dental appliances such as splints and night guards.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033632