OCT 15 2004

K041718

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. David Graver Great Lakes Orthodontics 800-828-7626
dgraver@greatlakesortho.com

DATE PREPARED: June 23, 2004

TRADE OR PROPRIETARY NAME: Keles facemask
COMMON NAME: Protraction Facemask
CLASSIFICATION NAME: Orthodontic Extraoral Headgear 872.5500
PRODUCT CODE: DZB

PREDICATE DEVICE: Nitom Facebow
Ortho Kinetics
1611A South Melrose Dr.
Vista, CA 92083

DEVICE DESCRIPTION
The Keles Facemask is an orthodontic headgear device. All components have been used in legally marketed devices or have been found to be safe for dental use.

INTENDED USE
The Keles Facemask is intended for the treatment of patients with Class III malocclusions

TECHNOLOGICAL CHARACTERISTICS COMPARED WITH PREDICATE DEVICE
The Keles Facemask and predicate consists of similar extraoral and intraoral components.

We conclude that the similarity in design between the Keles Facemask and the predicate device supports the safety and effectiveness of the Keles Facemask for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2004

Mr. David Graver
Manager
Great Lakes Orthodontics, Limited
200 Cooper Avenue
P.O. Box 5111
Tonawanda, New York 14151-5111

Re: K041718
Trade/Device Name: Keles Facemask
Regulation Number: 872.5500
Regulation Name: Extraoral Orthodontic Head
Regulatory Class: II
Product Code: DZB
Dated: June 23, 2004
Received: July 19, 2004

Dear Mr. Graver:

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.

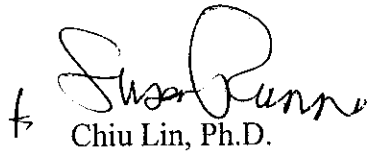
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 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 Lin, Ph.D.
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): K041716

Great Lakes Orthodontics
200 Cooper Avenue
Tonawanda, NY 14150

Device Name: Keles Facemask

Indications for Use:

The Keles protraction face mask is used in the treatment of patients with Class III malocclusions with a deficient or posteriorly positioned maxilla. The facemask is especially useful in patients with an anterior bite tendency or condition.

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: K041718