



KOS 3479

FEB 27 2009

## Great Lakes Orthodontics, LTD.

An Employee Owned Company

Our Vision

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

### 510(k) SUMMARY

CONTACT PERSON: Mark Lauren Great Lakes Orthodontics  
[mlauren@greatlakesortho.com](mailto:mlauren@greatlakesortho.com) 800-828-7626

DATE PREPARED: November 20, 2008

TRADE OR PROPRIETARY NAME: Biocryl X

COMMON NAME: Radiopaque dental acrylic, cold-cure acrylic

CLASSIFICATION NAME: Denture relining, repairing, or rebasing (872.3760)

PRODUCT CODE: EBI

PREDICATE DEVICE: Biocryl™ Great Lakes Orthodontics  
200 Cooper Avenue  
Tonawanda, NY 14150

#### DEVICE DESCRIPTION

Biocryl X is a radiopaque, auto-polymerizing powder/liquid dental acrylic system.

#### INTENDED USE

Biocryl X is intended for the laboratory fabrication of radiographic templates to be worn by a patient during x-ray imaging.

#### TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE

Biocryl X was evaluated as follows:

Mechanical properties, Hardness, Exotherm, Water absorption and extractables, and Working times.

Biocryl X was also evaluated as follows:

Agar Diffusion Assay	non-cytotoxic
Mucous Membrane Irritation	non-irritant
Klingman Maximization Test	non-sensitizer

We conclude that the similarity in comparison between Biocryl X and the predicate device, as well as the performance data and biocompatibility results, support the safety and effectiveness of Biocryl X for the indicated uses.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 27 2009

Mr. Mark Lauren  
Great Lakes Orthodontics, Limited  
200 Cooper Avenue  
P.O. Box 5111  
Tonawanda, New York 14151

Re: K083479  
Trade/Device Name: Biocryl X  
Regulation Number: 21 CFR 872.3760  
Regulation Name: Denture Relining, Repairing, or Rebasing Resin  
Regulatory Class: II  
Product Code: EBI  
Dated: December 19, 2008  
Received: December 19, 2008

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.

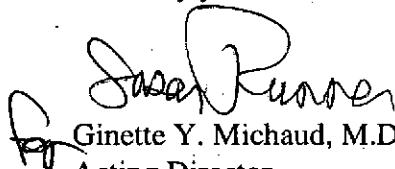
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

  
Ginette Y. Michaud, M.D.

Acting 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): K083479

Device Name: Biocryl X

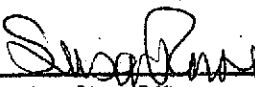
### Indications For Use:

Biocryl X is indicated for the fabrication of dental radiographic templates worn during x-ray imaging.

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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