K021121

MAY 2 8 2002

Aromacryl, LLC

1013 East Third Street, Royal Oak, MI 48067
(248) 544-0860

510(k) Summary

Date of Summary:	**March 27, 2002**
Submitter:	**Aromacryl, LLC**
Address:	**1013 East Third Street, Royal Oak, MI 48067**
Contact Person:	**Tanya L. Woods**
Telephone Number:	**(248) 544-0860**
Name of Device:	**Aromacryl flavored/fragranced Orthodontic Appliance**
Classification Name:	**Resin, denture, relining, rebasing**

The Aromacryl device is an orthodontic appliance using industry standard stainless steel wire and Aromacryl polymer and monomer. Aromacryl can be used to fabricate devices, such as orthopedic and functional appliances to correct malocclusions or post-treatment retention devices known as hawley retainers. The Aromacryl product offers the patient a pleasant tasting appliance by the addition of FDA approved food grade flavoring that is GRAS (Generally Recognized As Safe) for this application. The predicate substantially equivalent devices sited may have a somewhat plastic taste. The Aromacryl device would offer the patient a choice of an enjoyable flavor and fragrance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Tanya L. Woods
President
Aromacryl, LLC
1013 East Third Street
Royal Oak, Michigan 48067

Re: K021121
Trade/Device Name: Aromacryl
Regulation Number: 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: March 27, 2002
Received: April 08, 2002

Dear Ms. Woods:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Aromacryl's relining, repairing/rebasing resin is indicated for the fabrication of flavored/fragranced orthodontic appliances.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021121