AUG 2 9 2002

K022032

INOVATIV, LLC.

1155 TWIN HILLS DRIVE
JEFFERSON, OR. 97352
PHONE: 503-585-4362
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510 (K) Summary

Submitter Name:	Inovativ, LLC.
Submitter Address:	1155 Twin Hills Drive Jefferson, OR 97352
Submitter Telephone: Submitter Facsimile:	(503)585-4362 (503)585-1188
Contact Person:	Bob Bowers Chief Operating Officer
Date Summary Prepared:	June 10, 2002

SECTION 9: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(K) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR.807.92.

9.1 SUBMITTER INFORMATION

a. Company Name:	Inovativ, LLC.
b. Company Address:	1155 Twin Hills Drive Jefferson, OR 97352
c. Company Telephone: Company Facsimile:	(503)585-4362 (503)585-1188
d. Contact Person:	Bob Bowers Chief Operating Officer
e. Date Summary Prepared:	June 10, 2002

9.2 DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	Acetal
b. Classification Name:	Preformed Clasp 21 CFR 872.3285

9.3 IDENTIFICATION OF PREDICATE DEVICES

The Acetal material is a thermoplastic resin used to prefabricate partial denture clasps. This material is substantially equivalent to the Pressing North America, Inc. material, "Acetal Dental" Acetal resin. This material is commercially available in the United States.

9.4 DEVICE DESCRIPTION

The Acetal material is a thermoplastic resin that is used to fabricate dental prostheses. The resin is used in an injection molding or pressing device to fabricate the prostheses.

9.5 SUBSTANTIAL EQUIVALENCE

This material is substantially equivalent to the Pressing North America, Inc. material, "Acetal Dental" Acetal resin. The fundamental characteristics are similar: the Acetal thermoplastic resin is similar in design, function, physical properties and intended use to the predicate device.

9.6 INDICATIONS FOR USE

The Acetal is intended for the fabrication of temporary dental prostheses like preformed clasps using Inovativ, LLC Acetal.

9.7 TECHNOLOGICAL CHARACTERISTICS

A chemical analysis of the Acetal is provided within this submission. Both the Acetal and the predicate device are similar in design, material characteristics, physical properties, handling characteristics, intended use and functionality.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2002

Mr. Robert Bowers
Chief Operations Officer
Inovativ, LLC
1155 Twin Hills Drive
Jefferson, Oregon 97352

Re: K022032
Trade/Device Name: Acetal
Regulation Number: 21 CFR 872.3285
Regulation Name: Preformed Clasp
Regulatory Class: I
Product Code: EHP
Dated: June 10, 2002
Received: June 21, 2002

Dear Mr. Bowers:

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 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____K022032_____

Device Name_____Acetal_____

Indications for use:

The Acetal is intended for the fabrication of temporary dental prostheses like preformed clasps using Inovativ, LLC Acetal.

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Prescription Use ✓ OR Over the counter ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

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

510(k) Number: K022032