21.0 510(K) SUMMARY K061501

20.1 SUBMITTER INFORMATION JUL 26 2006

Submitter Name: Address and Telephone Number	ACI, Inc. 5830 Woodson. Ste3, Mission, KS 66202 Tel:(913) 220-2045 Fax:(775) 806-5580
Contact Person:	Charles Lee President
Date Summary Prepared:	May 2006

20.2 DEVICE IDENTIFICATION

Trade/Proprietary Name:	Flexo Dental Resin Material
Classification:	Denture relining, repairing or rebasing resin 872.3760

20.3 IDENTIFICATION OF PREDICATE DEVICES

Flexo Dental Resin Material is substantially equivalent to Lucitone FRS Flexibel Dental Resin, K992956, by Dentsply International.

20.4 DEVICE DESCRIPTION

The Flexo Dental Resin Material is an injection moldable, flexible thermoplastics resin designed for fabricating removable dental appliances. Physical property testing indicates that Flexo Dental Resin Material performs equal to the predicate device.

20.5 SUBSTANTIAL EQUIVALENCE

The Flexo Dental Resin Material is an injection moldable, flexible thermoplastics resin designed for fabricating removable dental appliances. The Flexo Dental Resin Material is substantially equivalent to other injection moldable material currently in commercial distribution such as Lucitone FRS Flexibel Dental Resin and Valplast Resin Material. For the purpose of this 510K, the Flexo Dental Resin Material will be shown to be substantially equivalent to the Lucitone FRS Flexibel Dental Resin , K992956, by Dentsply International.

20.6 INTENDED USE:

Flexo Dental Resin Material is used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

20.7 TECHNOLOGICAL CHARACTERISTICS

All of the components found in Flexo Dental Resin Material have been used in legally marketed device or have been found to be safe for dental use. The cytotoxic and biocompatible test has been performed(Non-cytotoxic).

We believe that the similarity in composition of Flexo Dental Resin Material to the predicate device, the performance data, and the results of biocompatibility testing support the safety and effectiveness of Flexo Dental Resin Material for the indicate uses.

CONCLUSION

The ACI Flexo Dental Resin Material is considered to be substantially equivalent in design, material and function to the Lucitone FRS Flexible Dental Resin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 2006

Mr. Charles Lee
President
ACI, Incorporated
5830 Woodson, Ste. 3
Mission, Kansas 66202

Re: K061501
Trade/Device Name: Flexo Dental Resin Material
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: May 30, 2006
Received: June 07, 2006

Dear Mr. Lee:

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" (21 CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

5.0 INDICATION FOR USE STATEMENT

510(k) NUMBER (IF KNOWN): K061501

DEVICE NAME: **Flexo Dental Resin Material**

INDICATION FOR USE:

Flexo Dental Resin Material is intended to fabricate partial or full removable dentures, as well as occlusal splints and night guards.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over –The-Counter-Use** ____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

Robert Betz DDS for Dr. Susan Runner

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...of Anesthesiology, General Hospital,
...ion Control, Dental Devices

...Number K061501