FEB 0 7 2002

K014141

Section 5-1

Contact: David Vozick

SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 190 and 21 CFR par 807.92

Trade Name: **EXTORAL/TESCERA GLAZING RESIN**
Common Name: **GLAZE**
Classification name: Denture, Relining, Repairing, or Rebasing Resin
Class II per 21 CFR 872.3760

Description of Applicant Device:
A single bottle glaze for use on indirect resin composite restorations.

Intended uses of Applicant Device:
Intended to be used primarily as a glaze on resin composites.

Predicate Devices: Jet Seal / Ortho-Jet Acrylic Resin K941925 (clearance date of 05/27/94)

Significant Performance Characteristics:

	EXTORAL/ TESCERA GLAZING RESIN	JET SEAL (ORTHO-JET ACRYLIC RESIN)
Intended Use	Resin sealant.	Resin sealant.
Product Description	Clear solution.	Clear solution.
Delivery System	Brush	Brush

Side by side comparisons of EXTORAL/TESCERA GLAZING RESIN to the predicate device Jet Seal (Ortho-Jet) clearly demonstrates that the applicant device is substantially equivalent to the legally marketed devices. The ingredients of EXTORAL/TESCERA GLAZING RESIN were tested for biocompatibility and were found to be non-toxic.
It is concluded that the information supplied in this submission has proven the safety and efficacy of EXTORAL/TESCERA GLAZING RESIN.

David Vozick
Chairman
AFP Imaging Corporation
1 914 592 6100

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 7 2002

Mr. David Vozick
Chairman
AFP Imaging Corporation
250 Clearbrook Road
Elmsford, New York 10523

Re: K014144
Trade/Device Name: Extoral/Tescera Glazing Resin
Regulation Number: 872.3310
Regulation Name: Coating Material for Resin Fillings
Regulatory Class: II
Product Code: EBD
Dated: December 14, 2001
Received: December 18, 2001

Dear Mr. Vozick:

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

510(k) Number (if known): K014144

Device Name: **EXTORAL/TESCERA GLAZING RESIN**

Indications For Use:

This product is used as a surface sealant for indirect composites.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K014144