

510K SUMMARY

Since all JBC's proposed monomers and polymers are products using the same chemical formulas and in some cases the same polymers and monomers as other currently manufactured and distributed denture based resins, it is the dyes and pigments that are an issue here.

All the monomers and polymers were subjected to all of the tests listed above in the premarket submission for physical characteristics and performances that would be consistent and/or different with the other commercially marketed monomers and polymers tested. The none clinical tests, simple as they were, appeared to show results that represented equal performances between the TESTER samples and the CONTROL samples.

All solvent dyes used, were used at percentages that were allowable for maintaining safe FDA levels of toxic ingredients. The same also applies for the use of the dry synthetic dye pigments used to tint the polymers.

Therefore, all pigments used, were used, where levels of toxic substances were acceptable and regarded as not to be a threat to public safety.

The physical wearing of dental appliances by family members showed no immediate or short terms side affects from any of the new polymers or monomers.

I had inquired with the Dental Division of the Food And Drug Administration and asked about obtaining leach testing for each of my products to determine the safeness of the dyes/pigments. I was told that the dyes/pigments would not leach out of the cured methyl methacrylate resin, but if any free nitrogen electrons/ions, present in the dyes/pigments could transfer to the soft tissues of the mouth.

I was instructed to include in my 510K Summary the chemical structures of the dyes/pigments being used in my products. Therefore, the chemical structures that I was able to obtain are included for that part of your review. The chemical structures that I

KR 74727

2

was unable to obtain are of proprietary property and can be obtained upon request from the dye/pigment manufacturer(s).

Any further steps towards the manufacturing or production, await acceptance from the Food and Drug Administration, Center for Devices and Radiological Health, for the manufacturing and marketing of the above mentioned products.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 1998

Ms. Priscilla L. Mier
Co-Owner
J.B.C. & Company
23691 Via Del Rio
Yorba Linda, California 92887

Re: K974727
Trade Name: Jet Acrylic Liquid-Monomer, Ortho Jet Powder
Polymer, Plastic
Regulatory Class: II
Product Code: EBI
Dated: December 16, 1997
Received: December 18, 1997

Dear Ms. Mier:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531

Page 2 - Ms. Mier

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/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

Page 1 of 2

510(k) Number (if known): K 974727

Device Name: Denture relining, repairing or rebasing resin.

Indications For Use:

See Enclosure...

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Suzanne Bunker
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number *K974727*

Prescription Use *Yes*
(Per 21 CFR 801.109)

OR

Over-The-Counter Use *No*

510K #
K974727
page 2/2

STATEMENT OF INTENDED USE

COMMERCIAL MARKET:

Because of the restricted nature of all dental resins, the commercial market for my dental products is solely going to be in the dental laboratory/dental office industry.

Methyl methacrylate monomer and polymer is used to form a hard acrylic plastic during the fabrication of dental appliances.

1. Orthodontic and Dental laboratories:
 - a. to be used by qualified dental/orthodontic technicians trained in the fabrication of orthodontic and pedodontic, fixed and removable appliances.
 - b. trained in the proper use, precautions and hazards of dental resins
 - c. the actual fabrication of these dental devices must first be preceded by an authorized prescription for such a device, by a licensed dental practitioner.
2. Dental Offices/Clinics
 - a. to be used by qualified dentists/dental assistants trained in the fabrication of orthodontic, pedodontic fixed and removable appliances.
 - b. to be used by qualified dentists/dental assistants trained in the proper use, precautions and hazards of dental resins
 - c. to be used under the direct supervision of a licensed dental practitioner