

K97354Q

FEB 10 1998

Pressing North America, Inc.  
4311 SW Research Way  
Corvallis, Oregon 97333  
541 754 1238 PHONE  
541 754 7478 FAX

# Pressing North America, Inc.

September 15, 1997

## 510(k) Summary

This is to notify you of the intention of Pressing North America, Inc. to import and distribute the following device for:

Pressing Di Monticelli Italy  
Via Emilia Romagna 233  
47033 Cattolica, Italy  
011 378909948 Phone  
011 378909958 Fax  
Stefano Monticelli, Administrator  
Establishment #9026751

Contact person for Pressing North America, Inc. (submitter): Thomas D. Maddux,  
4311 SW Research Way, Corvallis, Oregon, 97333. Phone 541 754 1238, Fax 541  
754 7478

Proprietary Name: MASKY

Common or Usual Name: Tooth shade resin material

Establishment Registration Number: 3031160

Classification name: 872.690

Performance Standard: Unknown

Substantial Equivalence: This product is similar in design, composition, and function to ArtGlass, manufactured by Hereaus Kulzer which was the subject of Premarket Notification #K954115.

**Intended Use:** To cover exposed portions of metallic frameworks in partial denture prostheses, for more natural appearance.

**Technological Characteristics:** Resin material that is biologically inert once cured on the metallic framework, similar to ArtGlass, with exception of curing methodology. ArtGlass cures by light; Masky by heat.

**Clinical Performance Summary:** Both ArtGlass and Masky are biologically inert once cured; tests as performed by the Istituti Ortopedici Rizzoli for Pressing Italy on the material address standard tests for biocompatibility. The tests, performed in December 1996, are enclosed in this 510(k) application; as follows:

1. EVALUATION OF CHROMOSOMAL ABERRATIONS INDUCED IN VITRO BY HEAT CURING RESIN FOR THE COVERING OF CrCo PROSTHESES;
2. EVALUATION OF THE EFFECT OF HEAT CURING RESIN FOR THE COVERING OF CrCo PROSTHESES ON CELL VIABILITY USING PROPIDIUM IODIDE UPTAKE;
3. MUTAGENICITY OF HEAT CURING RESIN FOR THE COVERING OF CrCo PROSTHESES IN THE AMES SALMONELLA / MICROSOME TEST;
4. EVALUATION OF SISTER CHROMATID EXCHANGE IN VITRO INDUCED BY HEAT CURING RESIN FOR THE COVERING OF CrCo PROSTHESES.

**Clinical Performance Conclusions:** Masky had no negative results in testing that contraindicates use with dental prostheses.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 10 1998

Mr. Thomas D. Maddux  
Corporate Secretary  
Pressing DI Monticelli Rag. Stefano  
C/O Pressing North America Incorporated  
4311 SW Research Way  
Corvallis, Oregon 97333

Re: K973542  
Trade Name: Masky  
Regulatory Class: II  
Product Code: EBI  
Dated: January 28, 1998  
Received: January 30, 1998

Dear Mr. Maddux:

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.

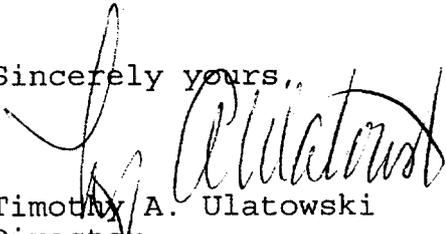
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 premarket notification submission does not affect any obligation you might have under sections 531

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

510(k) Number (if known): K973542

Device Name: Masky

Indications For Use:

**Statement of Indications for Use:**

Masky is indicated for use when patients require a partial denture prosthetic that has a substantial amount of exposed metal in the frame. Masky covers exposed metal areas to reduce visual impact of framework in the mouth. Can also cover wires used in orthodontic appliances to make appliances less visible.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Sharon Rimmer*  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K973542

Prescription Use Yes  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No