K083701

510(K) Summary

JAN - 9 2009

A. Submitter Information

Submitter's Name:	Kettenbach GmbH & Co. KG
Address:	Im Heerfeld 7 D-35713 Eschenburg, Germany
Phone Number:	(+49) 2774-705-58
Fax Number:	(+49) 2774-705-33
Contact Person:	Michaela Zinke
Date of Preparation:	December 10, 2008

B. Device Name

Trade Name: *Panasil® Impression Materials*, to include:

- *Panasil® initial contact (regular, regular fast, light, light fast, x-light, x-light fast)*
- *Panasil® tray (fast 1:1, soft fast 5:1, soft fast 1:1)*

Common/Usual Name: Impression Material

Classification Name: Material, Impression (21 CFR 872.3660, Product Code: ELW)

C. Predicate Devices

Trade Name: Panasil® Impression Materials (K082560)

D. Device Description

Panasil® Impression Materials are addition-curing, elastomeric materials with hydrophilic properties, high tear strength, dimensional accuracy, and resistance to permanent deformation. The *Panasil Impression Materials* include four different viscosities (heavy-bodied, medium-bodied, light-bodied, x-light-bodied), available in an assortment of delivery systems: traditional 1:1 50 ml automix cartridge and 5:1 362 ml foil bags for use in most automatic dispensing and mixing systems.

E. Intended Use

The *Panasil® Impression Materials* are intended to:

- be placed on an impression tray (or injected directly into the mouth, depending on the technique and device) and used to reproduce the structure of a patient's teeth and gums;
- provide models for study and for production of restorative prosthetic devices.

Indications for Use

Panasil® initial contact (regular, regular fast, light, light fast, x-light, x-light fast) is to be used as a syringeable impression material for:

- Two-step putty-wash impression technique.
- One-step putty-wash impression technique.
- One-step impression technique using a foil (plastic putty spacer).
- One-step impression technique (simultaneous technique) using dual viscosities.
- Reline impressions.
- Fabricating full or partial dentures.

Panasil® tray (fast 1:1, soft fast 5:1, soft fast 1:1) is to be used as a heavy-bodied material for:

- One-step impression technique (simultaneous technique) using single or dual viscosities.
- Two-step impression technique using dual viscosities.
- Functional impressions.

F. Technological Characteristics Summary

The technological characteristics of the *Panasil® Impression Material* subject devices *(Panasil® initial contact, Panasil® tray)* are substantially equivalent to the *Panasil Impression Material* predicate devices' technological characteristics. The subject devices and the predicate devices are addition-curing, elastomeric materials, designed and manufactured for use as dental impression materials.

G. Performance Data

No performance standards have been established for this type of device. *Panasil® Impression Material* subject devices *(Panasil® initial contact, Panasil® tray)* have been evaluated in accordance with the applicable criteria established in *Guidance for Industry and FDA Staff: Dental Impression Materials – Premarket Notification (FOD#2203, 8/17/1998)* and *ISO 4823 (Dentistry – Elastomeric impression materials):2000/Cor. 1:2004/Amd. 1:2007*. The results of performance testing demonstrated that *Panasil Impression Material* subject devices *(Panasil initial contact, Panasil tray)* are suitable for use as dental impression materials. *Panasil Impression Material* subject devices *(Panasil initial contact, Panasil tray)* have been designed and manufactured to perform in a manner substantially equivalent to that of the *Panasil Impression Material* predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kettenbach GmbH & Company KG
C/o Ms. Kristi Kistner
President
Pacific Otter Works, Incorporated
975 Veronica Springs Road
Santa Barbara, California 93105

JAN - 9 2009

Re: K083701
Trade/Device Name: Panasil® Initial Contact (regular, regular fast, light, light fact, x-light, x-light fact) Impression Material, Panasil® Tray (fast 1:1, soft fast 5:1, Soft fast 1:1) Impression
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: December 10, 2008
Received: December 15, 2008

Dear Ms Kistner:

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.

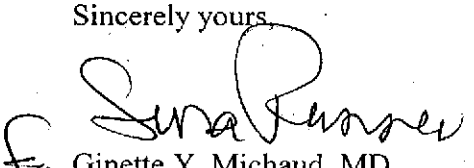
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



Ginette Y. Michaud, MD
Acting 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 (if known) K083701

Device Name *Panasil® initial contact (regular, regular fast, light, light fast, x-light, x-light fast)* Impression Material

Indications for Use

Panasil initial contact (regular, regular fast, light, light fast, x-light, x-light fast) is to be used as a syringeable impression material for:

- Two-step putty-wash impression technique.
- One-step putty-wash impression technique.
- One-step impression technique using a foil (plastic putty spacer).
- One-step impression technique (simultaneous technique) using dual viscosities.
- Reline impressions.
- Fabricating full or partial dentures.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K083701

Indications for Use

510(k) Number (if known) K083701

Device Name *Panasil® tray (fast 1:1, soft fast 5:1, soft fast 1:1)* Impression Material

Indications for Use

Panasil tray (fast 1:1, soft fast 5:1, soft fast 1:1) is to be used as a heavy-bodied material for:

- One-step impression technique (simultaneous technique) using single or dual viscosities.
- Two-step impression technique using dual viscosities.
- Functional impressions.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

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