

K130647

Heraeus

510(k) Summary according to 21 CFR 807.92(c)

MAY 17 2013

Submitter Information:	
Name	Heraeus Kulzer, LLC
Address	300 Heraeus Way South Bend, IN 46614
Phone Number	(574) 299- 5421
Fax Number	(574) 291- 0080
Establishment Registration Number	1925223
Name of Contact Person	Jamie Mearna
Date Prepared	December 31, 2012
Name of Device:	
Trade or Proprietary Name	Xantasil
Common or Usual Name	Impression Material
Classification Name	Dental ELW
Device Classification	Class II
Classification Panel:	76 Dental
Regulation:	21 CFR 872.3660
Product code (s):	ELW
Legally marketed device(s) to which equivalence is claimed:	Flexitime K000629 Flexitime Monophase Pro Scan K113574
Reason for 510(k) Submission:	This submission is to notify FDA of an optimized A-silicone impression material with medium consistency meant as a replacement for alginates.
Device Description:	Xantasil is an addition-curing polyvinyl-siloxane impression material. Xantasil is delivered in 50 ml and 380 ml cartridges. Xantasil is an optimized A-silicone impression material with medium consistency meant as a replacement for alginates. The mouth removal time for the product is 1.5 minutes Xantasil is for use in the Dynamix automatic dispensing and mixing system and the 1:1 Cartridge dispenser.
Indications for use:	Xantasil is a medium flow, addition-curing, elastomer dental impression material that can be used to cover all impression needs where a traditional alginate material would be used, such as impressions for temporaries, crown and bridges, removable dentures, orthodontic models, opposing jaw models, splints, mouth guards and bleaching trays. It is used to get a negative copy of the patients' dental situation.

Summary of the Technological Characteristics of the New Devices Compared to the Predicate Devices Flexitime Monophase K000629 & Flexitime Monophase K113574:

The physical properties of Xantasil like Flexitime Monophase (K000629) and Flexitime Monophase ProScan (K113574) are in compliance with ISO 4823.

Similarities as Compared to Predicates:

Attribute	Xantasil	Monophase K000629	Monophase Pro Scan K113574
FDA Code	ELW	ELW	ELW
Mixing Time, hand spatulated	n.a.	n.a.	n.a.
Working Time	≥2:30 min	≥2:30 min	≥2:30 min
Detail Reproduction	≤20 μm	≤20 μm	≤20 μm
Linear Dimensional Change	≤1,5%	≤1,5%	≤1,5%
Compatibility to Gypsum	≤20 μm	≤20 μm	≤20 μm
Strain in Compression	≤20%	≤20%	≤20%

Differences as Compared to Predicate:

No difference in technological characteristics.

Results Summary:

Xantasil is substantially equivalent to Flexitime Monophase ProScan and Flexitime Monophase. All of the products are indicated for taking impression materials of suited techniques.

Conclusions Drawn From Non-Clinical and Clinical Data:

The biological compatibility of Xantasil was verified utilizing bridging data from predicates in accordance with the international standard ISO 10993-1.

The biocompatibility of Xantasil in the aforementioned indication was documented in a biocompatibility evaluation report and the benefit/risk relation has been judged as positive.

The clinical evaluation is intended to critically evaluate the clinical benefits of the medical device in comparison to its potential risks. Therefore, any clinical evaluation is part of the compulsory risk management process according to EN ISO 14971, and critical findings must further be considered in the current risk management process of the medical device manufacturer responsible for the evaluated device.

On this background, the clinical evaluation was performed. This critical evaluation followed the procedures outlined in the corresponding clinical evaluation plan.

Considering the evaluated scientific data and technical results for Xantasil it is concluded that the products can be expected to exhibit the claimed technical performance and that potential undesirable clinical effects and risks seem well controlled and accepted, when weighed against their benefit to dentistry. Therefore, a positive benefit versus risk ratio can be stated by the experts for Xantasil, provided that the products applied in accordance with its intended use as outlined in the manufacturer's instructions for use.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 17, 2013

Ms. Jamie Mearna
Associate Quality Assurance/Regulatory Affairs Manager
Heraeus Kulzer, Limited Liability Company
300 Heraeus Way
SOUTH BEND IN 46614

Re: K130647
Trade/Device Name: Xantasil
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: March 7, 2013
Received: March 20, 2013

Dear Ms. Mearna:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

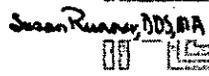
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
cn=Mary S. Runner -S,
0.9.2342.19200300.100.1.1=1300087
950/
Date: 2013.04.26 07:48:52 -04'00'

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130647

Device Name: Xantasil

Indications for Use:

Xantasil is a medium flow, addition-curing, elastomer dental impression material that can be used to cover all impression needs where a traditional alginate material would be used, such as impressions for temporaries, crown and bridges, removable dentures, orthodontic models, opposing jaw models, splints, mouth guards and bleaching trays. It is used to get a negative copy of the patients' dental situation.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
Susan Runner, DDS, MA 2013:04.24 07:37:07
04'00'

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

Page 1 of 1

510(k) Number: K130647