DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

3M Deutschland GmbH
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

October 31, 2017

Re: K173318
Trade/Device Name: Rapid HB, Rapid LB, Rapid MB
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression material
Regulatory Class: Class II
Product Code: ELW
Dated: October 18, 2017
Received: October 20, 2017

Dear Mr. Mark Job:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Mary S. Runner -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Rapid HB
Rapid LB
Rapid MB

Indications for Use *(Describe)*

- Impressions of inlay, onlay, veneer, crown, and bridge preparations
- Fixation and implant impressions

RAPID HB, MB and LB are especially suitable for taking impressions of single-unit and double-unit preparations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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3M Deutschland GmbH

Carl-Schurz-Straße 1
41453 Neuss
Germany

Postal Address:
ESPE Platz
82229 Seefeld
Germany

☎+49 (0)8152 700-0
🖷+49 (0)8152 700-1366
Internet: www.3M.de/OralCare
E-Mail: info3MESPE@3M.com
WEEE-Reg.-Nr. DE 36963167
VAT-ID: DE 120679179

510(k) Summary K173318

Submitter:..... 3M Deutschland GmbH
ESPE Platz
82229 Seefeld
Germany
Establishment Registration Number: 9611385

Contact Person ..... Ruediger Franke
..... Regulatory Affairs Specialist
..... Phone: +49-8152-700 1802
..... Fax: +49-8152-700 1869
..... e-mail: ruediger.franke@3M.com
Date: ..... October 4, 2017

Trade Name: ..... Rapid HB
..... Rapid LB
..... Rapid MB

Common Name: ..... Polyether impression material

Classification Name:..... Impression material
..... (21 CFR 872.3660, product code ELW)

Device Class: ..... Class II

Predicate Devices ..... Impregum Penta Soft Quick Step HB (K032001)
..... Impregum Penta Soft Quick Step MB (K032001)
..... Impregum Soft Quick Step LB (K032001)

Description of Device

Rapid HB, Rapid LB and Rapid MB are a group of polyether impression materials of heavy, light and medium consistency used by dental professionals individually or in combination. Rapid HB and Rapid MB are mixed in the Pentamix mixing device, while Rapid LB can be applied directly using the Garant dispenser.

Rapid HB is a heavy bodied hydrophilic impression material used in one step technique. Thereby Rapid HB is used in combination with the light consistency wash material Rapid LB. Rapid HB is reddish-violet colored.

Rapid LB is a light bodied hydrophilic impression material used in one step technique. Thereby Rapid LB is used in combination with the higher consistency tray material Rapid HB. Rapid LB is apple green colored.
Rapid MB is a medium bodied hydrophilic impression material used in mono-phase technique (Rapid MB as syringing and as tray material) and in one step technique (Rapid LB as syringing and Rapid MB as tray material). Rapid MB is blueish-violet colored.

Applicable Standards for Product Tests

- ISO 4823: Dentistry — Dentistry – Elastomeric Impression Materials

Indications for Use for Rapid HB, Rapid LB and Rapid MB

• Impressions of inlay, onlay, veneer, crown, and bridge preparations
• Fixation and implant impressions

RAPID HB, MB and LB are especially suitable for taking impressions of single-unit and double-unit preparations.

Comparison

Rapid HB, Rapid LB and Rapid MB were compared to Impregum Penta Soft Quick Step MB and Impregum Soft Quick Step LB regarding indications for use, intended use, composition technology and physical and mechanical properties.
The tables below summarize the indications and technology of Rapid HB, Rapid LB and Rapid MB and predicate devices:

Indications Comparison	**Rapid HB Rapid LB Rapid MB**	**Predicate Devices (K032001)**
Indications for Use (from the Indications for Use form)	• Impressions of inlay, onlay, veneer, crown, and bridge preparations • Fixation and implant impressions RAPID HB, MB and LB are especially suitable for taking impressions of single-unit and double-unit preparations.	**Impregum Penta Soft Quick Step HB**
		Poly Q Penta H: Tray material for dual phase impression techniques.
		Impregum Soft Quick Step LB
		Poly Q Garant L: Wash material for dual phase impression techniques.
		Impregum Penta Soft Quick Step MB
		Poly Q Penta M: Impression material for monophase technique.
Intended Use	Intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums	Intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums

Table Comparison of indications

The differences between the indications of the Rapid materials and the predicate devices are not critical to the intended clinical use because the Rapid indications described the clinical case whereas the predicate indication described the usable impression technique of each material. All clinical indications (inlay, onlay, veneer, crown, and bridge preparations as well as fixation and implant impressions) are achievable with the described impression techniques (dual phase and monophase technique). This difference, i.e., stating clinical cases rather than impression techniques, does not raise any new questions regarding safety or effectiveness. Rather, it clarifies the appropriate uses within the described impression techniques and does not expand the indications of the new device(s) beyond those of the predicate device(s).

Technology	**Rapid HB Rapid LB Rapid MB**	**Impregum Penta Soft Quick Step HB Impregum Penta Soft Quick Step MB Impregum Soft Quick Step LB (K032001)**
Light bodied material offered in Garant cartridge system with mixing ratio of base and catalyst pastes 2:1 (by volume) The pastes are mixed using Garant mixing tips or Intra-oral syringe.	x	x
Medium and Heavy bodied material offered in Penta foil bags with mixing ratio of base and catalyst paste 5:1 (by volume). The pastes are mixed in automatic mixing machine of the Pentamix family and Penta mixing tip.	x	x
Material family	Polyether material	Polyether material
Setting characteristic	super quick	quick

Table Comparison to Predicate Technology

Rapid HB, Rapid LB and Rapid MB, Impregum Penta Soft Quick Step HB, Impregum Penta Soft Quick Step MB and Impregum Soft Quick Step LB are Polyether based Precision Impression materials. Chemically they are based on polyalkyleneoxides which cure by a cationic ring-opening polymerization mechanism which is initiated by a Sulfonium starter. However, Rapid materials have been developed with the goal to accelerate the curing mechanism by adjusting the initiator system. Additives like fillers, softeners, pigments etc. have been adjusted accordingly.

Non-clinical testing

In vitro testing was conducted to show that Rapid HB, Rapid LB and Rapid MB fulfils the requirements of FDA recognized standard ISO 4823. Additionally, the performance of Rapid HB, Rapid LB and Rapid MB was compared to the predicate devices Impregum Penta Soft Quick Step HB, Impregum Penta Soft Quick Step MB and Impregum Soft Quick Step LB regarding consistency, contact angle, working time, intraoral setting time, recovery from deformation, strain in compression, detail reproduction, compatibility with gypsum type 3 / type 4 and linear dimensional change. The results of Rapid HB, Rapid LB and Rapid MB fulfill the requirements of ISO 4823 and are similar to Impregum Penta Soft Quick Step HB, Impregum Penta Soft Quick Step MB and Impregum Soft Quick Step LB. In summary, 3M Deutschland GmbH concludes that Rapid HB, Rapid LB and Rapid MB is substantially equivalent to the predicate devices regarding performance and physical and mechanical properties.

Biocompatibility

The biocompatibility assessment for the products was conducted in accordance with the following guidance:

Guidance	**Edition**	**Title**
US FDA Docket Number FDA-2013-D-0350. CDRH Document Number 1811	June 16, 2016	Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process - Guidance for Industry and Food and Drug Administration Staff
ISO 10993-1	2009	Evaluation and testing within a risk management process
ISO 10993-5	2009	Tests for *in vitro* cytotoxicity
ISO 10993-10	2010	Tests for irritation and skin sensitization
ISO 10993-11	2006	Tests for systemic toxicity
ISO 10993-12	2012	Sample preparation and reference materials
ISO 10993-18	2005	Chemical characterization of materials
ISO 7405	2008/Amd 1: 2013	Evaluation of biocompatibility of medical devices used in dentistry

The biocompatibility of Rapid HB, Rapid LB and Rapid MB has been assessed by a board-certified toxicologist according to recommendations in FDA guidance and internationally recognized standards for medical and dental devices. The conclusion of the assessment is that Rapid HB, Rapid LB and Rapid MB are safe for their intended use.

Conclusion

Comparisons of the indications for use/intended use, composition, technology, and physical and mechanical properties showed that the Rapid HB, Rapid LB and Rapid MB group of materials is as safe, as effective, and performs as well as or better than the legally marketed devices Impregum Penta Soft Quick Step HB, Impregum Penta Soft Quick Step MB and Impregum Soft Quick Step LB.