



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

April 13, 2016

3M Deutschland GmbH
Ruediger Franke
ESPE Platz
Seefeld, Bavaria 82229
GERMANY

Re: K153174
Trade/Device Name: Ketac Universal Aplicap
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental cement
Regulatory Class: Class II
Product Code: EMA
Dated: March 14, 2016
Received: March 16, 2016

Dear Mr. Ruediger Franke:

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 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>. 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,

A handwritten signature in black ink that reads "Susan Runno DDS, MA". The signature is written in a cursive style. In the background, there is a faint, large watermark of the letters "FDA" in a stylized font.

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
---	---

510(k) Number (if known)

Device Name
Ketac Universal Aplicap

Indications for Use (Describe)

- Linings for single-surface and multiple-surface composite fillings
- Core build-up prior to crown placement
- Primary tooth fillings
- Stress bearing Class I restorations with at least one additional support outside of the filling area
- Stress bearing Class II restorations when the isthmus is less than half of the intercuspal distance and with at least one additional support outside of the filling area
- Cervical fillings, if aesthetics is not the prime consideration
- Single-surface and multiple-surface temporary fillings
- Fissure sealing

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
 Food and Drug Administration
 Office of Chief Information Officer
 Paperwork Reduction Act (PRA) Staff
 PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

**510(k) Summary**

510(k) 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: March 14, 2016

Trade Name: Ketac Universal Aplicap

Common Name: Glass ionomer restorative material

Classification Name: Dental cement
(21 CFR 872.3275, product code EMA)

Device Class: Class II

Predicate Devices Equia (K091106)

Description of Device

Ketac Universal Aplicap is a radiopaque glass ionomer restorative delivered in capsules used for bulk fillings. It can be applied without lining; releases fluoride ions and is available in various shades corresponding to the Vita™ Classical color system.

Applicable Standards for Product Tests

- ISO 9917-1: Dentistry-- Water-based cements - Part 1: Powder/liquid acid-base cements
- ISO 29022: Dentistry - Adhesive - Notched Edge Shear Bond Strength Test

Indications for Use for Ketac Universal Aplicap

- Linings for single- and multiple-surface composite fillings
- Core build-up prior to crown placement
- Primary tooth fillings
- Stress bearing Class I restorations with at least one additional support outside of the filling area
- Stress bearing Class II restorations when the isthmus is less than half of the intercuspal distance and with at least one additional support outside of the filling area
- Cervical fillings, if aesthetics is not the prime consideration
- Single- and multiple-surface temporary fillings
- Fissure sealing

Comparison

Ketac Universal Aplicap	Equia (Predicate Device, (K091106, by GC)	Comparison
Stress bearing Class I restorations with at least one additional support outside of the filling area	Class I restorations	More restrictive and conservative Class I indication for Ketac Universal Aplicap despite comparable mechanical properties
	Non-stress bearing Class II restorations	Despite comparable mechanical properties this indication is not claimed by 3M Deutschland GmbH
Stress bearing Class II restorations when the isthmus is less than half of the intercuspal distance and with at least one additional support outside of the filling area	Stress bearing Class II restorations when the isthmus is less than half of intercuspal distance	More restrictive and conservative Class II indication for Ketac Universal Aplicap despite comparable mechanical properties
Single- and multiple-surface temporary fillings	Intermediate restorative	Same indication but different wording.
Cervical fillings, if aesthetics is not the prime consideration	Class V and root surface restorations	Same indication but different wording.
Core build up prior to crown placement	Core build-up	Same indication but different wording.
Linings for single- and multiple-surface composite fillings	-	Indication is not separately claimed by GC. The indication linings can be viewed as a small Class I/Class II restorations with reduced mechanical performance requirements.

Ketac Universal Aplicap	Equia (Predicate Device, (K091106, by GC)	Comparison
Primary tooth fillings	-	Indication is not separately claimed by GC. The indication for use in primary tooth fillings emphasizes that the material is suitable for use for use in children.
Fissure sealing	-	Indication is not separately claimed by GC. The indication fissure sealing is comparable with a small Class I indication.

Table Comparison of indications

Despite comparable mechanical properties between the two products 3M Deutschland GmbH uses a more restrictive and conservative range for Ketac Universal Aplicap for stress bearing Class I and Class II indications in comparison to GC America for Equia. The restriction to recommend additional support from outside the filling area will give additional support to the filling and therefore reduce the stress.

The indications for use in temporary filling, Class V restorations and core build-ups are equivalent for Ketac Universal Aplicap and the predicate device but with a slightly different wording.

Additional comments to Indication subset not claimed by GC

- Linings for single- and multiple-surface composite fillings
- Fissure sealing
- Primary tooth fillings

All three indications are subsets of the listed indications in table Comparison of indications. Linings for single-surface and multiple-surface composite fillings are only a thin layer under a protective composite filling material. Therefore, linings can be considered as small Class I/ Class II restorations with reduced mechanical performance requirements.

The indication for use in fissure sealing is comparable with a small Class I indication.

The indication for use in primary tooth fillings emphasizes that the material is suitable for use in children.

These subset indications claimed for Ketac Universal Aplicap are not claimed by GC but don't influence the safety and efficacy of the device Ketac Universal Aplicap because the mechanical requirements for the material are fully covered by the other indications listed in the table Comparison of indications.

In summary, it can be stated that all listed indications of Ketac Universal Aplicap are equivalent to the predicate device Equia with no new or increased indication.

	Ketac Universal Aplicap	Equia (Predicate Device, (K091106, by GC)	Comparison
Essential Ingredients	Polyacrylic Acid, Oxide Glass Chemicals, Water, and Tartaric Acid	Polyacrylic Acid, Oxide Glass Chemicals, Water, and Tartaric Acid	equivalent
Powder/liquid compounds delivered in capsules	X	X	equal
Glass polyalkenoate cement according ISO 9917-1: 2007	X	X	equal
Use of conditioner	No	X	It has been demonstrated that a conditioner does not increase the bonding strength of Ketac Universal Aplicap
Use of coat	Possible according IFU, but not mandatory	X	It has been demonstrated that a coat does not increase the surface hardness of Ketac Universal Aplicap.

Table Comparison of essential ingredients and technology

Ketac Universal Aplicap and Equia are glass polyalkenoate cements compliant with ISO 9917-1: 2007 delivered in capsules. The essential ingredients of both products are polyacrylic acid, oxide glass chemicals, water, and tartaric acid. The main difference in the application of Ketac Universal Aplicap to the predicate device Equia is that for Ketac Universal Aplicap neither a coat nor the use of conditioner is required. It has been shown that the use of a coat does not increase the surface hardness of Ketac Universal Aplicap. Further it has been demonstrated that a conditioner does not increase the bonding strength. In Summary, both products are glass polyalkenoate cements with similar composition and technology. Additional coating or conditioning steps did not lead to superior properties (surface hardness, adhesion) for Ketac Universal Aplicap.

In vitro testing was conducted to examine consistency, maximum solubility, dimensional change, working and setting time, bonding strength, fluoride release, compressive strength, 3-point flexural strength, and surface hardness comparing the performance of Ketac Universal Aplicap to Equia.

Properties	Ketac Universal Aplicap	Equia (Predicate Device, (K091106, by GC)	Comparison
Consistency /mm	14	16	There is no guidance or standard available to refer to. The consistency of Ketac Universal Aplicap (14 mm) and Equia (16 mm) is comparable.
Maximum solubility /%	0.11	0.06	The solubility as single property is not addressed by a standard or guidance. The solubility of Equia is lower than that of Ketac Universal Aplicap but both materials have a solubility on a low level that does not effect biocompatibility or mechanical properties. Moreover, Ketac Universal Aplicap meets the ISO 9917-1:2007 requirement with no acid soluble arsenic or lead content (0.00 mg/kg).
Dimensional change, 24 hours /%	0.24	0.16	The dimensional change as single property is not addressed by a standard or guidance. The change of length of Ketac Universal Aplicap is low and comparable to Equia at 24 hours and at 72 hours. Based on the accuracy of the test method it is concluded that the changes of lengths of Ketac Universal Aplicap are comparable to those of Equia.
Dimensional change, 72 hours /%	0.18	0.12	
Working time /min:sec (in-house method)	1:48	1:12	The working time as single property is not addressed by a standard or guidance. The working time according the in-house method of Ketac Universal is higher than for Equia. It generally depends on the preference of the dentist. A longer working time provides the dentist with more time to handle the material.
Setting time /min:sec (in-house method)	2:42	2:12	The setting times for Ketac universal Aplicap and Equia were evaluated according ISO 9917:2007. Both are within the limit of 1.5 – 6.0 minutes. The setting times according to the in-house method are for Ketac Universal Aplicap and Equia only slightly different to the times stated in the instruction for use. Ketac Universal Aplicap has longer setting time than Equia. Also for this material property the ideal working and setting times depend on the preferences of dentists.
Setting time /min:sec (ISO 9917:2007)	2:30	1:43	

Properties	Ketac Universal Aplicap	Equia (Predicate Device, (K091106, by GC)	Comparison
Bonding strength, enamel /MPa	5.7	5.0	Equia and Ketac Universal Aplicap have comparable adhesion values on human enamel.
Bonding strength, dentin /MPa	5.1	10.0	The adhesion of Equia on dentin is higher compared to Ketac Universal Aplicap. The review of clinical literature was presented in the 510(k). The literature showed that bonding strength of Ketac Universal Aplicap is sufficient for use. Therefore, this difference has no significant impact.
Fluoride release, 1 day /ppm	4.0	5.9	The fluoride release rate as single property is not addressed by a standard or guidance. Ketac Universal Aplicap and Equia release fluoride ions over a time period of at least 12 months. The release of Equia is higher than Ketac Universal Aplicap during the first month. Afterwards the release rates are comparable.
Fluoride release, 1 week /ppm	8.7	13.5	
Fluoride release, 2 weeks /ppm	11.4	-	
Fluoride release, 1 month /ppm	14.8	21.5	
Fluoride release, 3 months /ppm	22.4	30.4	
Fluoride release, 6 months /ppm	29.2	38.6	
Fluoride release, 9 months /ppm	35.1	44.6	
Fluoride release, 12 months /ppm	39.8	49.4	
Compressive Strength (ISO 9917-1) /MPa	188	200	Ketac Universal Aplicap and Equia show comparable values according to the ISO method and both are above the limit of 100 MPa for glass polyalkenoate cements. Ketac Universal Aplicap shows a higher compressive strength than Equia according the modified method of ISO 9917-1 which should be beneficial for the longevity.
Compressive Strength (In-house method) /MPa	251.4	206.7	
3-Point Flexural Strength /MPa	50.2	46.4	The flexural strength as single property is not addressed by a standard or guidance for water based glass ionomer cements. Ketac Universal Aplicap and Equia have similar 3-point flexural strengths.
Surface Hardness 24 hours /MPa	667.0	498.7	The surface hardness as single property is not addressed by a standard or guidance. Ketac Universal Aplicap shows a higher surface hardness than Equia which should be beneficial for the longevity.

Table Comparison of physical and mechanical properties

In case of dimensional change, 3-point flexural strength and bonding strength to enamel the values for both devices are nearly identical. The adhesion of Equia on dentin is higher compared to Ketac Universal Aplicap. However, a clinical literature review showed that a performance in the range of Ketac Universal Aplicap are clinically sufficient. With respect to fluoride release Equia shows a higher rate in the first month and a comparable rate to Ketac Universal Aplicap thereafter. With respect to consistency, working time and setting time these properties show slightly differences depending on the preferences of the dentist. Both materials have a solubility on a low level that does not effect biocompatibility. The compressive strength (according in-house method) and the surface hardness of Ketac Universal Aplicap exhibited higher values than the predicate device Equia which should lead to higher longevity of the restoration.

Biocompatibility

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

- 1) Testing guidelines outlined in the FDA General Program Memorandum G95.
- 2) ISO 10993-1:2009(E) Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process; in addition, relevant detailed guidance in ISO Standards 10993-3:2014 (Tests for genotoxicity, carcinogenicity and reproductive toxicity), 10993-5:2009 (Tests for in vitro cytotoxicity), 10993-10:2010 (Tests for irritation and skin sensitization); and 10993-11:2006 (Tests for systemic toxicity) was considered;
- 3) ISO 7405:2008 / Amd 1:2013 Dentistry-- Evaluation of Biocompatibility of Medical Devices in Dentistry; and
- 4) Japan: PFSB/ELD/OMDE Notification No. 0301-1 Mar. 1, 2012; (as translated by 3M Health Care Japan, August 6, 2012).

The biocompatibility of Ketac Universal Aplicap 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 Ketac Universal Aplicap is safe for its intended use.

Conclusion

Comparisons of indications for use, essential ingredients, technology, and physical and mechanical properties showed that Ketac Universal Aplicap is substantially equivalent to the predicate device.