DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 4, 2015

Exacta Dental Direct Inc.
c/o Mr. Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, CT 60803

Re: K142446
Trade/Device Name: FixTemp Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: February 28, 2015
Received: March 6, 2015

Dear Mr. Keen:

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 yours,

for 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

4. Indications for Use Statement

510(K) Number (If k_____no 510(K) number assigned__ K142446 **Name: *FixTemp ™ Cement***

INDICATIONS FOR USE

FixTemp ™ Cement is a dental luting agent indicated for:

- temporary cementation of provisional crowns and bridges,
- cementing of semi-permanent implants.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) **Concurrence of CDRH, Office of Device Evaluation (ODE)**		
Prescription Use __XXX____	**or**	**Over - The - Counter Use** **_____** **(Per 21 CFR 801.109)**
		(Optional Format 1-2-96

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Concurrence of CDRH, Office of Device Evaluation (ODE)

5. 510(k) Summary

(per 21 CFR 807.92)

28 May 2015

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Proprietary Name:	Fixtemp Cement
Common Name	Fixtemp Cement
Device Classification Name	Dental Cement
Classification Number:	21 CFR 872.3275
Product Code	EMA
Reviewing Group	Dental Devices Panel
Device Classification	Class II
Establishment registration No.	Owner/Operator 9043538/ Registration # 1836392
Predicate Device	K110759/ TempoCem / DMG USA, Inc.

Device Description

The Fixtemp Cement is designed as a luting cement for temporary dental applications. This dental cement having the active ingredients of zinc oxide does not include Eugenol. This lack of Eugenol does not reduce structural properties but allows a choice among healthcare professionals where Eugenol can cause objectionable results.

Indications For Use

FixTemp ^{tm} Cement is a dental luting agent indicated for:

- temporary cementation of provisional crowns and bridges,
- cementing of semi-permanent implants.

Intended Use

The intended use of the Fixtemp Cement is as a dental luting agent for use in interim dental restorations to retain temporary restorations.

The scientific concept on which this device is based is the principle that a chemical reaction with zinc oxide forms an adhesive bond to act as a dental luting agent. This device functions by creating adhesion by chemical action.

		Fixtemp Cement

5. 510(k) Summary

(per 21 CFR 807.92)

Substantial Equivalence

Exacta Dental Direct, Inc. has determined that the Fixtemp Cement is substantially equivalent to the performance of a predicate Device. Fixtemp Cement is equal to this predicate. The differences between these devices are incidental and not significant. Both devices use similar technological characteristics and principles.

Testing

The Fixtemp Cement has benefited from design, development, testing and production procedures that conform to ISO 13485 Quality Systems.

Testing has confirmed this device meets its product specification. A series of factory tests are conducted to verify the intended signals are accurate and can maintain performance over its useful life. Testing has established this device is equal to predicate medical device in terms of working time, setting time, film thickness, and compressive strength (see comparison table).

Conclusion

There are no substantial differences between the Fixtemp Cement defined in this 510(k) submission and the stated predicate device. This device is equal to predicates currently used in other similar medical devices.

Exacta Dental Direct, Inc. continues to search all appropriate sources for information relating to safety and effectiveness and maintains an in-house reporting device to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

		Fixtemp Cement

Table 12-1 Substantially Equivalent Comparison to Predicate.doc
comparison of the FixTemp ™ Cement to the predicate: TempoCem K110759

Description/Feature	Predicate Device TempoCem K110759	FixTemp Cement	Similarity	Difference	Comment
regulatory requirements					
Description	temporary luting cement containing Eugenol that is based on zinc oxide in double cartridges	Eugenol free, temporary luting cement based on zinc oxide in double cartridges		Different	The absence of Eugenol simply eliminates the depression of sensitivity.
Classification Name:	Dental cement	Dental cement	Same		Both devices are dental cements
Classification	II	II			Both devices are subject to same FDA regulation.
Regulation Number	21 CFR 872.3275 (a)	21 CFR 872.3275 (b)	Same		Both are subject to same FDA regulations
Product Code	EMB	EMA		Different	Product codes reflect presence or absence of Eugenol
Difference related to Eugenol	pleasant clove taste oil	Eugenol may inhibit future dental procedures		Different	Some practitioners prefer Eugenol and some avoid it.
Indications for Use	Indicated for temporary cementation of crowns and bridges or provisional cementation of crowns and bridges on implant abutments	Indicated for luting of temporary dental prosthesis (crowns, inlays, onlays)	Same		
Intended Use	Temporary luting and cementation of temporary crowns and bridges	Temporary luting and cementation of temporary crowns and bridges	Same		
What condition does it treat?	Applied directly on the temporary restoration and into the cavity.	Applied directly on the temporary restoration and into the cavity.	Same		

Table 12-1 Substantially Equivalent Comparison to Predicate.doc
comparison of the FixTemp ™ Cement to the predicate: TempoCem K110759

Description/Feature	Predicate Device TempoCem K110759	FixTemp ™ Cement	Similarity	Difference	Comment
characteristics					
Compliance to standard	ISO3107	ISO3107	same		
container	double cartridge or syringe	double cartridge or syringe	same		
Dispenser	injector / syringe	injector / syringe	same		
Paste Ratio	1:1 ?	1:1	same		
Appearance	Homogeneous and smoothly consistent	Homogeneous and smoothly consistent	same		
Film Thickness (ISO 3107)	Less than 20 µm	Less than 20 µm	same		
Setting Time (ISO 3107)	4 min	Approx. 4 – 7 min	same		
Compressive strength (ISO 3107)	8 MPa	More than 8MPa	same		
temporary cement	yes	yes	same		
temporary cementation of provisional crowns & bridges	yes	yes			
cementing of semi-permanent crown or bridges on top of implants	yes	yes	same		
Meets ISO 3107:2004	yes	yes	same		
Working time	1 minute	More than 1 min	same		
Storage	Room temperature, dry (15-25°C)	Room temperature, dry (15-25°C)	Same		
applications					
What is the treatment environment?	Applied directly on the temporary restoration and into the cavity.	Applied directly on the temporary restoration and into the cavity.	Same		
Is device a treatment device?	Yes	Yes	Same		
What patient population does this apply?	for temporary tooth filling, to affix dental devices such as crowns or bridges, or to be applied to a tooth to protect the tooth pulp	for temporary luting cements to affix dental prosthesis such as crowns or bridges, inlays and onlays	Same		
Anatomical Sites	all human teeth	all human teeth, except allergies	Same		Same

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