December 18, 2024

Teknimed SAS
℅ Barry Sands
President and Founder
RQMIS, Inc.
110 Haverhill Road
Suite 524
Amesbury, Massachusetts 01913

Re: K242216
Trade/Device Name: Gentafix® (1, 3, 3MV)
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: LOD, MBB
Dated: December 12, 2024
Received: December 12, 2024

Dear Mr. Sands:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JESSE MUIR -S
Digitally signed by JESSE MUIR -S
Date: 2024.12.18 16:16:45 -05'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242216

Device Name

GENTAFIX® (1, 3, 3MV)

Indications for Use *(Describe)*

GENTAFIX is indicated for use as bone cement in arthroplasty procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is intended for use to affix a new prosthesis in the second phase of a two-stage revision after the initial infection has been cleared.

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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"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 – K242216

TEKNIMED's GENTAFIX

A. SUBMITTER'S ADDRESS, TELEPHONE NUMBER, CONTACT PERSON

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Date Prepared: June 13, 2024

B. SUBJECT DEVICE

Trade/proprietary name of device:	GENTAFIX (1,3, 3MV)
Common or Usual Name:	Bone Cements
Classification Name:	Polymethylmethacrylate (PMMA) Bone Cement
Regulation Number:	21 CFR 888.3027
Classification:	Class II
Product Code:	MBB, LOD

C. PREDICATE DEVICES

Primary Predicate:

- CEMEX GENTA
- K092773
- LOD, MBB
- 21 CFR 888.3027
- Class II

D. DEVICE DESCRIPTION

Teknimed's GENTAFIX® cements with gentamicin are a family of surgical cements of various viscosities, each containing the antibiotic gentamicin. GENTAFIX® bone cements are intended for fixation of prosthetic components into bone medullar cavity in cemented arthroplasty procedures. GENTAFIX® can be used with the Teknimed's own Class I 510(k) exempt accessories: bowl and spatula, and a Vacuukit® vacuum mixing and injection system. Following are the GENTAFIX models identified based on their viscosities:

- GENTAFIX® 1 is a high viscosity bone cement intended for digital use.
- GENTAFIX® 3 is a low viscosity bone cement intended for syringe application.
- GENTAFIX® 3 MV is a medium viscosity bone cement intended for syringe application.

E. INDICATIONS FOR USE

GENTAFIX is indicated for use as bone cement in arthroplasty procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is intended for use to affix a new prosthesis in the second phase of a two-stage revision after the initial infection has been cleared.

F. TECHNOLOGICAL CHARACTERISTICS

Each unit of bone cement consists of a polymeric powder component and a monomeric liquid component. The powder contains benzoyl peroxide (BPO) and the liquid contains N, N-dimethyl-ρ-toluidine (DMPT). When the liquid is added to the powder and mixed in accordance with the instructions for use, a cement of a given consistency depending on formulation is formed.

The BPO from the powder and DMPT from the liquid react to generate free radicals by means of a redox reaction. The free radicals react with the monomeric liquid, causing

polymerization and hardening. The surgeon applies the cement either digitally or by a syringe applicator, inserting the prosthesis into the cement when it is in a doughy state. The cement dough then hardens, polymerizing exothermally in-situ and securing the prosthesis in place.

G. TECHNOLOGICAL CHARACTERISTICS COMPARISON

The subject device, GENTAFIX, and the primary predicate, Cement Genta (a.k.a Cemex Genta) (K092773), have identical indications for use/intended use. The subject and the primary predicate bone cements have equivalent material and the same technological characteristics and principle of operation. The performance of the subject device was found to be equivalent to the primary predicate device. Both the subject device and predicate bone cements are made of Polymethymethacrylate (PMMA) with Gentamicin, are used for identical indications (i.e., for revision surgeries), and are provided sterile in different viscosities.

The only difference between the subject device and the primary predicate is the subject device liquid component has a co-monomer in addition to the Methylmethacrylate, while the primary predicate liquid component has Methylmethacrylate as a monomer. This difference does not raise additional questions of safety and efficacy, since the co-monomer is part of the methacrylate family and biocompatibility, physical, chemical and mechanical testing of the final finished GENTAFIX bone cement proves the device is safe and effective.

H. PERFORMANCE DATA

Following performance testing of the worst-case GENTAFIX bone cement was conducted:

- Physical and chemical characteristics tests such as mixing & application, viscosity, chemical composition characterization, antibiotic release test, leachable, molecular weight and polymer structure identification test, morphology, stability, and thermal properties.
- Mechanical properties test: Modulus test (4-point bending, tension), Dynamic tension-compression fatigue, and Monomer elution testing from curing bone cement and cured bone cement, long-term antibiotic elution profile.
- Other non-clinical tests: Sterilization validation, biocompatibility, endotoxin and pyrogenicity, shelf-life.

The subject device test results met the acceptance criteria and were found to be equivalent to the predicate device. Physical, chemical characteristics and mechanical tests were conducted as per FDA special control requirements "Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement."

I. CONCLUSION

The technological differences between the subject device and the primary predicate (K092773) do not raise new questions of safety and effectiveness. Any differences in technological characteristics have been tested and documented. The subject device and primary predicate (K092773) have been determined to be equivalent in terms of indications for use, materials, performance, sterility, and biocompatibility.