K103433

510(k) Summary
for the F20

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the F20

Date Prepared: November 15, 2010

JAN - 3 2011

1. **Submitter:**
Teknimed SAS
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France

Contact Person:
J.D. Webb
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Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** F20
Common Name: Polymethylmethacrylate (PMMA) bone cement
Classification Name: Cement, Bone, Vertebroplasty
Class II per 21 CFR section 888.3027
NDN

3. **Predicate or legally marketed devices which are substantially equivalent:**
F20 is a modification of the following bone cements:
Vertecem (K090435, Teknimed)
Opacity+ (K080873, Teknimed)
Spine-Fix® (K045593, Teknimed)

4. **Description of the device:**
The purpose of this submission is to submit a new bone cement that is a modification of Vertecem and Opacity+ bone cements, previously cleared on K090435 and K080873, respectively. F20 has the same indications for use as the predicate devices. Another similarity is that the cement is made of two sterile components: the polymer in powder and the liquid monomer. These two components are in a double sterile packaging. Each unit contains a sterile ampoule of liquid within a blister pack and a powder within a double peelable pouch, the whole being packaged in a box. F20 is a self-hardening and ready to use bone cement with a high amount of radiopaque agent for percutaneous vertebroplasty. Like its predicates F20 allows an excellent consolidation of the vertebral body and an effective and rapid pain relief.

Materials:
The liquid component is mainly composed of methyl methacrylate. The major powder components are polymethylmethacrylate (PMMA) . Benzoyl peroxide which initiates the polymerization is included in the polymer powder.

5. **Substantial equivalence claimed to predicate devices**

F20 is substantially equivalent to the Vertecem, Opacity+ and Spine-Fix® in terms of intended use, design, materials used, mechanical safety and performances. The table below compares the features and characteristics of theF20 to these predicate devices.

Device Name / Items	F20	Vertecem	Opacity+	Spine-Fix®
Sponsor	Teknimed	Teknimed	Teknimed	Teknimed
510(k) Number	--	K090435	K080873	K045593
Device Classification Name	Cement	Bone	Vertebroplasty	Cement

Items \ Device Name	F20	Vertecem	Opacity+	Spine-Fix®
Product Code	NDN	NDN	NDN	NDN
Regulation #	Class II per 21 CFR section 888.3027	Class II per 21 CFR section 888.3027	Class II per 21 CFR section 888.3027	Class II per 21 CFR section 888.3027
Indications for Use	see below	same	same	same
Chemical Composition	PMMA based w/ methylmethacrylate	PMMA based w/ methylmethacrylate	PMMA based w/ methylmethacrylate	PMMA based w/ methylmethacrylate
Compressive strength	per ISO 5833	per ISO 5833	per ISO 5833	per ISO 5833
Dynamic testing	performed	performed	performed	performed
Flexural strength	per ISO 5833	per ISO 5833	per ISO 5833	per ISO 5833
Flexural modulus	per ISO 5833	per ISO 5833	per ISO 5833	per ISO 5833

6. **Intended Use:**

The F20 is used for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures of the vertebral body may result from osteoporosis, benign lesions (hemangioma), or malignant lesions (metastatic cancers, myeloma).

The Vertecem Bone Cement is used for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures of the vertebral body may result from osteoporosis, benign lesions (hemangioma), or malignant lesions (metastatic cancers, myeloma).

The Opacity+ is intended for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures of the vertebral body may result from osteoporosis, benign lesions (hemangioma), or malignant lesions (metastatic cancers, myeloma).

Spine Fix cement is used for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

7. **Non-clinical Test Summary:**

The following tests were conducted:

- Chemical Composition
- Powder morphology
- Molecular weights
- handling times
- Compressive strength
- Dynamic fatgue test compression
- Flexural strength
- Flexural modulus
- Viscosity or extrusion forces during the injection phase
- Setting time vs. temperature
- Radiopacity
- Monomer elution testing

Test data indicate that the final properties of F20 are stable and in compliance with the standard reference for bone cement: ISO 5833 "implants for surgery - acrylic resin cements" and are similar to predicate devices.

8. **Clinical Test Summary:**

No clinical studies were performed

9. **Conclusions Nonclinical and Clinical:**

The F20 Cement is substantially equivalent to Vertecem, Opacity+ and Spine-Fix®. The modifications do not change the intended use or fundamental scientific technology of the device and do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Teknimed SAS
% The OrthoMedix Group, Inc.
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

JAN - 3 2011

Re: K103433
Trade/Device Name: F20
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN
Dated: December 20, 2010
Received: December 27, 2010

Dear Mr. Webb:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: F20

Indications For Use:

The F20 is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures of the vertebral body may result from osteoporosis, benign lesions (hemangioma), or malignant lesions (metastatic cancers, myeloma).

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103433