K070293

5. 510(K) SUMMARY AS REQUIRED BY 21 CFR 807.92

Submitter:
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JUL 10 2007

Contact:
Laurent Schaller, President
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Date Summary was Prepared: July 9, 2007

Device Proprietary Name:	Benvenue VCF Osteo Coil System
Regulation Number:	888.4540
Classification Name:	Orthopedic Manual Surgical Instrument
Device Product Code:	OCJ

Predicate Device(s): The Benvenue VCF Osteo Coil System is substantially equivalent to the following devices:

Device & Manufacturer	Manufacturer	510(k) No. or status
ARCUATE ™ Vertebral Augmentation System (ARC ™ Osteotome instrument)	Medtronic Sofamor Danek	K063248
Radial Disc Cutter Accessory within the Trans-sacral Spinal Access & Preparation Device	Trans1, Inc	K032891
Spineology Bone Reamer	Spineology, Inc.	Class I Exempt
KINSA Suture Anchor	Smith & Nephew, Inc	K061154

Device Description:
The Benvenue VCF Osteo Coil System is packaged as a single-use, sterile, non-implantable device. It is a surgical instrument designed to be used in percutaneous applications, for the creation of channels within the existing spinal bone structure for the flow of polymethylmethacrylate bone cement (PMMA). The Benvenue VCF Osteo Coil System consists of three primary components: Nitinol Osteo Coil, Deployment Cannula with PEEK liner, and Handle. The nitinol Osteo Coil is pre-set into a loop shape and can be temporarily straightened into a cannula for deployment into cancellous bone. Once positioned in the cancellous bone, the Osteo Coil is advanced forward out of the cannula. The surgeon controls the amount of Osteo Coil deployment with the use of the handle, which allows for incremental deployment and directional control. Upon exiting the cannula, the Osteo coil regains it

loop shape as it channels through the cancellous bone. The device is available in two sizes. This system does not include the bone cement.

Statement of Intended Use:

> The Benvenue VCF Osteo Coil System is indicated for the treatment of pathological compression fractures of the vertebral body that may result from osteoporosis, benign lesions, and/or malignant lesions, by creating channels in the existing spinal bone structure for the flow of polymethylmethacrylate bone cement (PMMA).

Discussion of Nonclinical Tests:

The safety and performance of the Benvenue VCF Osteo Coil System have been substantiated through extensive non-clinical testing. Results of testing show that the Benvenue VCF Osteo Coil System can reliably and safely perform as intended in the treatment of pathological compression fractures of the vertebral body, by creating channels within the existing spinal bone structure in preparation for the flow of polymethylmethacrylate bone cement (PMMA). No new questions of safety or effectiveness have been raised

Substantial Equivalence:

The Benvenue VCF Osteo Coil System product information, technological comparison to predicate products, and test results demonstrate that the Benvenue VCF Osteo Coil System is safe and performs as intended. The Benvenue VCF Osteo Coil System is substantially equivalent to the currently marketed predicate devices with respect to intended use, materials and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BENVENUE MEDICAL, INC.
% Mr. Laurent Schaller
President
1235 Pear Ave., Suite 111
Mt. View, California 94043

JUL 10 2007

Re: K070293
Trade/Device Name: Benvenue VCF Osteo Coil System
Regulation Number: 21 CFR 888.4540
Regulation Name: Orthopedic manual surgical instrument
Regulatory Class: Class I
Product Code: OCJ
Dated: May 31, 2007
Received: June 5, 2007

Dear Mr. Schaller:

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.

We note that your device exceeded the Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 CFR Part 888.9), and therefore required the submission and clearance of a premarket notification prior to commercial distribution in the United States. Future devices of this same type, that meet the exemption criteria and do not exceed the limitations of exemptions found in 21 CFR Part 888.9 will be exempt from the premarket notification requirements of the Act.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address:
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Bruehup
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070293

Device Name: Benvenue VCF Osteo Coil System

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K070293