5. 510(k) Summary

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SUMMARY

Submitter's name:	Vidacare Corporation
Address:	722 Isom Road San Antonio, TX 78216
Phone:	210-375-8500
Fax number:	210-375-8537

NOV 21 2008

Name of contact person:	Grace Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 Fax: 949-552-2821

Date the summary was prepared: November 4, 2008

Name of the device:	Vertebral Access System by Vidacare®
Trade or proprietary name:	Vertebroplasty System
Common or usual name:	Cement Dispenser Conduit for Vertebroplasty
Classification name:	Injector, vertebroplasty (does not contain cement)
Classification	Class I 21 CFR sec. 888.4200 Injector, vertebroplasty (does not contain cement). And 21CFR sec. 878.4820 Surgical instrument motors and accessories/attachments.
Product Code	OAR and MOQ

K081713

The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

	510(k) Number		***Trade or Proprietary or Model Name***		***Manufacturer***
1	K072045	1	EZ-IO® Bone Marrow Biopsy System	1	Vidacare Corp.
2	K051820	2	Parallax EZFlow Cement Delivery System	2	Parallax Medical

Description of the device:

The Vertebral Access System by Vidacare® consists of a reusable Power Driver and a disposable sterile needle set in a sealed tray. The sealed tray contains 1 coupler with driver sterile sleeve, 1 beveled needle set and 2 sharps protectors. The Vertebral Needle Set is an 11 gauge, 152 mm cannula made of 304 stainless steel, with beveled cutting tip and stylet. The 11 gauge, 152mm needle set is identical in gauge and length to the predicate devices: OnControl™ Bone Marrow Biopsy System (cleared via K072045) and the Parallax EZFlow Cement Delivery System (cleared via K051820). The powered driver is identical to the predicate driver cleared via K072045.

Indications:

The Vertebral Access System by Vidacare® is intended for use with a standard cement delivery system for the fixation of fractures of the vertebral body using vertebroplasty. This system does not contain cement.

Summary of the technological characteristics of our device compared to the predicate device:

The predicates and the Vidacare Vertebral Access System were compared in the following areas and found to have similar technological characteristics and to be equivalent.

Indications for Use
Target Population
Driver Design Features
Needle Design
Technique
Sterility
Biocompatibility
Anatomical Sites
Where Used

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vidacare Corporation
% Regulatory Specialists, Inc.
Ms. Grace Holland
Regulatory Specialist
3722 Avenue Sausalito
Irvine, California 92606

NOV 21 2008

Re: K081713
Trade/Device Name: Vertebral Access System by Vidacare®
Regulation Number: 21 CFR 878.4820
Regulation Name: Surgical instrument motors and accessories/attachments
Regulatory Class: I
Product Code: MOQ, OAR
Dated: November 7, 2008
Received: November 10, 2008

Dear Ms. Holland:

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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/industry/support/index.html.

Sincerely yours,

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

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K081713

Device Name: Vertebral Access System by Vidacare®

Indications for Use:

The Vertebral Access System by Vidacare® is intended for use with a standard cement delivery system for the fixation of fractures of the vertebral body using vertebroplasty. This system does not contain cement.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Page 1 of 1

510(k) Number K081713