FEB 17 2006

K051525 000256

## 510(k) SUMMARY

**SPONSOR NAME:** Amedica Corp.
615 Arapeen Drive
Suite 302
Salt Lake City, Utah 84108

**510(k) CONTACT:** Robert M. Wolfarth
Phone: (801) 583-5100
E-Mail: Robert@AmedicaCorp.com

**TRADE NAME:** Arx™ Spinal System

**COMMON NAME:** Ceramic Bone Fixation Appliance

**CLASSIFICATION:** Spinal Intervertebral Body Fixation Orthosis (Product Code 87 MQP) are Class II per 21 CFR §888.3060, reviewed by the Orthopedic Devices panel.

**PREDICATE DEVICES:**

- Medtronic Sofamor Danek Spinal Mesh
- Hedrocel Vertebral Body Replacement
- DePuy Acromed VBR System
- DePuy Acromed Stackable Cage System
- Medtronic Sofamor Danek VERTE-STACK Spinal System
- Synthes Vertebral Spacer System
- Scient'x Ellys and Aurys VBR
- DePuy Acromed Surgical Titanium Mesh System
- EBI Ionic Spine Spacer System

**DEVICE DESCRIPTION:**
The ARX Spinal System acts as a spacer to maintain proper vertebral body spacing and angulation following a partial or total corpectomy. The device is surgically implanted between vertebral bodies from an anterior, anterior-lateral, or lateral surgical approach. The ARX Spinal System is manufactured from $MC^2$, a ceramic material. The ARX Spinal System is for single level anterior spinal use from T1 to L5.

**INTENDED USE:**
The ARX Spinal System is intended for vertebral body replacement to aid in surgical correction and stabilization of the spine. The device is indicated for use in the thoracolumbar spine (T1 to L5) to replace or restore height a collapsed, damaged, diseased, or unstable vertebral body or portion thereof, excised as a result of tumor or trauma (i.e., fracture). It is indicated to achieve decompression of the spinal cord and neural tissues, and to restore the height of a collapsed or damaged vertebral body.

The ARX Spinal System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

The ARX Spinal System is always to be used with supplemental internal spinal fixation. Additionally, the ARX Spinal System may be used with bone graft.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**
Performance tests, design comparisons, and functional analyses conducted on the Arx Spinal System demonstrate that it is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2006

Mr. Robert M. Wolfarth
Director of Regulatory Affairs and Quality Assurance
Amedica Corporation
615 Arapeen Drive, Suite 302
Salt Lake City, Utah 84108

Re: K051525
Trade/Device Name: Arx™ Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: January 30, 2006
Received: January 31, 2006

Dear Mr. Wolfarth:

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 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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting 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): K051525

Device Name: Arx™ Spinal System

Indications for Use:

The ARX Spinal System is intended for vertebral body replacement to aid in surgical correction and stabilization of the spine. The device is indicated for use in the thoracolumbar spine (T1 to L5) to replace or restore height a collapsed, damaged, diseased, or unstable vertebral body or portion thereof, excised as a result of tumor or trauma (i.e., fracture). It is indicated to achieve decompression of the spinal cord and neural tissues, and to restore the height of a collapsed or damaged vertebral body.

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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**



*(Posted November 13, 2003)*

**510(k) Number** _____