

510(k) Summary
for the Foundation Interbody Devices

K073440

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

Date Prepared: February 4, 2008

APR 24 2008

1. **Submitter:**

Corelink LLC
1547 Fencorp Dr.
Fenton, MO 62206

Contact Person:

J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:**

Foundation Interbody Devices

Common Name:

intervertebral body fusion device

Classification Name:

intervertebral body fusion device - cervical
intervertebral body fusion device - lumbar
21 CFR 888.3080

Class II

ODP

MAX

3. **Predicate or legally marketed devices which are substantially equivalent:**

BAK/C Vista Interbody Fusion (P980048 S003)

BRANTIGEN I/F CAGE (P960025)

4. **Description of the device:**

The interbody fusion with autogenous bone graft solves and provides a logical solution for discal diseases once the movement of the vertebral segment is eliminated. The theoretical principles of the interbody cages are based on the following foundations:

1. Mechanical function, allows restoration of the intervertebral disc height and immediate stability of the mobile segments.
2. Biological function, related to the autogenous bone graft introduction into and around the cage, facilitates the interbody fusion.

The posterior Foundation Cage was developed as an implant for the posterior stabilization of the lumbar spinal column with the technique of Posterior Lumbar Interbody Fusion (PLIF).

The anterior Foundation Cage was developed as an implant for the posterior stabilization of the lumbar spinal column with the technique of Anterior Lumbar Interbody Fusion (ALIF).

The Foundation Cervical cage is a trapezoidal shape footprint for central placement in the vertebral body from an anterior approach.

Materials:

PEEK Optima® conforming to ASTM F2026

5. **Intended Use:**

Foundation™ Cervical Interbody Devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Foundation™ Cervical implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone. Foundation Cervical implants are to be used with

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supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Foundation™ Lumbar Interbody Devices are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Foundation™ Lumbar implants are to be used with autogenous bone graft and implanted via an open anterior or posterior approach. Foundation™ Lumbar implants are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices:

The Foundation Interbody Devices are similar in design, material, and intended use to their predicate devices that have been cleared by FDA for intervertebral body fusion.

7. Summary of Nonclinical Tests

Tests performed according to ASTM F2077 indicate that the Foundation Interbody Devices meet required mechanical strengths.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

The OrthoMedix Group, Inc.
% Mr. J.D. Webb
1001 Oakwood Blvd.
Round Rock, TX 78681

APR 24 2008

Re: K073440
Trade/Device Name: Foundation™ Interbody Devices
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX, ODP
Dated: April 9, 2008
Received: April 21, 2008

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.

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.

Page 2 – Mr. J.D. Webb

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

Indications for Use

510(k) Number (if known): K073440

Device Name: Foundation™ Interbody Devices

Indications for Use:

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The Foundation™ Lumbar Interbody Devices are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Foundation™ Lumbar implants are to be used with autogenous bone graft and implanted via an open anterior or posterior approach. Foundation™ Lumbar implants are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. [Signature]
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K073440