DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2000

Mr. Ben Shappley
President & CEO
OrthoMatrix, Inc.
711 Chaney Cove
Collierville, Tennessee 38017

Re: K001254
Trade Name: OrthoMatrix, Inc. Cerclage System
Regulatory Class: II
Product Code: JDQ
Dated: September 11, 2000
Received: September 14, 2000

Dear Mr. Shappley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D. for
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE OF THE DEVICE

Device Name: OrthoMatrix, Inc. Cerclage System with Cable, Trochanteric Grip, Plate and Crimp

Indications for Use:

The OrthoMatrix, Inc. Cerclage System is indicated in situations where they are utilized to cerclage and attach various objects which include the following applications:

1. Spinal trauma surgery – the cables can be used in sublaminar, interspinous, or facet wiring techniques.
2. Spinal re-constructive surgery – the cables are incorporated into constructs for the purpose of correction of spinal deformities; such as scoliosis, kyphosis and spondylolisthesis, etc.
3. Spinal degenerative surgery – the cables may be used as an adjunct to spinal fusions.
4. Orthopaedic trauma surgery – the cables are used to secure fractures of the olecranon, patella, femur, and the ankle.
5. Orthopaedic re-constructive surgery – the cables are used to attach the greater trochanter after trochanteric osteotomy after total hip arthroplasty.
6. Cardiovascular surgery – closure of the sternum following sternotomy.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)

_____ for
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001254