

DEC 30 1998

K983622

BodyForm™ Thoraco-Lumbar Fixation System

510 (k) Summary

Company: Theken Surgical
1100 Nola Avenue
Barberton, Ohio 44203

Trade Name: BodyForm™ Thoraco-Lumbar Fixation System

Classification: Spinal Intervertebral Body Fixation Orthosis. Class II.

Description: The BodyForm™ Thoraco-Lumbar Fixation System is a construct which consists of one plate, contoured to match the lateral profile of the thoraco-lumbar vertebral bodies, four Morse taper headed screws, and two locking set screws. Plates are designed specifically to particular graft heights, with anatomic limitations in mind.

Performance Data:**Non-clinical:**

Testing was conducted according to ASTM F-1717-96. Properties of stiffness, strength, and fatigue life were characterized.

Intended Use:

The BodyForm Thoraco-Lumbar Fixation System is intended for treatment of anterior thoraco-lumbar spinal instability caused by:

1. Trauma.
2. Tumor.
3. Degenerative Disc Disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
4. Anterior fusion following multiple failed posterior fusion operations, including pseudoarthrosis.

The instrumentation is designed for levels of fixation from T10 to L4.

Substantial Equivalence:

Z-Plate Anterior Fixation System (Sofamor-Danek)
University Plate Titanium Anterior System (Acromed)
Anterior Thoracolumbar Locking Plate (Synthes)



DEC 30 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Lukas Eisermann
Director, Regulatory Affairs
Theken Surgical
1100 Nola Avenue
Barberton, Ohio 44203

Re: K983622

Trade Name: BodyForm Thoraco-Lumbar Fixation System
Regulatory Class: II
Product Code: KWQ
Dated: October 13, 1998
Received: October 15, 1998

Dear Mr. Eisermann:

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 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 (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.

Page 2 -- Mr. Eisermann

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,


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

Enclosure

510 (k) Number (if known): K983622

Device Name: **BodyForm™ Thoraco-Lumbar Fixation System**

1. Indications for Use:

The BodyForm Thoraco-Lumbar Fixation System is intended for treatment of anterior thoraco-lumbar spinal instability caused by:

1. Trauma.
2. Tumor.
3. Degenerative Disc Disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
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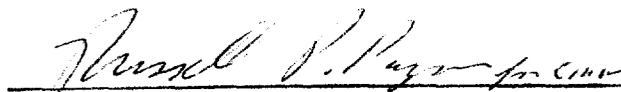
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1/2/96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983622