510(k) Summary

Pursuant to 21 CFR 807.92c

Submitted By: Andrew Rodenhouse
Transcorp, Inc.
1000 100th St. SW Suite F
Byron Center, MI 49315
Ph: 616-877-4177
Fax: 616-877-4522

Date: May 20, 2010

Device Information:

Trade Name: Transcorp Trans-Plate Anterior Cervical Plate System
Common Name: Spinal Intervertebral Body Fixation Orthosis
Classification: 21 CFR Section 888.3060, Product Code KWQ, Class II

Predicate Devices:

K030866 Synthes CSLP
K021461 Medtronic Atlantis Cervical Plate System

Device Description:

The Transcorp Trans-Plate Anterior Cervical Plate System includes various size anterior cervical plates and bone screws. The anterior cervical plate system includes a cover plate that covers the bone screws and the "window" of the plate. The cover plate is manufactured from implant grade PEEK conforming to ASTM F2026-08. The plates, screws, and cover plate locking blade are manufactured from Titanium Alloy conforming to ASTM F136-08. The plate is fixated by attaching screws through holes in the plate to the anterior portion of the vertebral body of the cervical spine (C2-C7).

Intended Use:

The Transcorp Trans-Plate Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2-C7). These implants have been designed to provide stabilization to cervical fusion. Indications for the use of this implant system include degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, or failed previous fusion.

WARNING: The Transcorp Trans-Plate Anterior Cervical Plate System in not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Performance Data:

Performance testing was performed on the Transcorp Trans-Plate Anterior Cervical Plate System. Static torsion, static bending compression, and dynamic bending compression were performed per ASTM F1717. A wear testing analysis was performed to determine particulate generation and wear debris was collected and analyzed per ASTM F1877. No clinical testing was performed.

Substantial Equivalence:

The Transcorp Trans-Plate Anterior Cervical Plate System is equivalent to the predicate devices in design, function, and indications for use. The results of non-clinical testing and analysis demonstrate that the mechanical performance of the Transcorp Trans-Plate Anterior Cervical Plate System is equivalent to the predicate devices. Thus, the Transcorp Trans-Plate Anterior Cervical Plate System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

MAY 21 2010

Transcorp, Inc.
% Mr. Andrew Rodenhouse
Principle Engineer
1000 100th Street SW, Suite F
Byron Center, Michigan 49315

Re: K092695
Trade/Device Name: Transcorp Trans-Plate Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: May 18, 2010
Received: May 19, 2010

Dear Mr. Rodenhouse:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use Statement

510(k) Number: K092695

Device Name: Transcorp Trans-Plate Anterior Cervical Plate System

Indications for Use:

The Transcorp Trans-Plate Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2-C7). These implants have been designed to provide stabilization to cervical fusion. Indications for the use of this implant system include degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, or failed previous fusion.

WARNING: The Transcorp Trans-Plate Anterior Cervical Plate System in not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Prescription Use X or Over-the-counter use _____
(per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092695