510(k) Summary

Submitter Name: GS Medical Co., Ltd
Submitter Address: 12 F Kolon Digital Tower Aston, 505-14 Gasan-Dong, Geumcheon-gu, Seoul, Korea
Phone Number: 82-2-2082-7777
Fax Number: 82-2-2082-7778
Contact Person: Dong Yong, Kim
Date Prepared: June 3, 2009
Device Trade Name: AnyPlus Spinal Fixation System

Common Name
- Spinal interlaminar fixation orthosis
- Spinal intervertebral body fixation orthosis
- Pedicle Screw spinal system

Classification Name, Class
- Class II: appliance, fixation, spinal interlaminal, 888.3050, KWP
- Class II: appliance, fixation, spinal intervertebral body, 888.3060, KWQ
- Class II/Class III: orthosis, spondylothesis spinal fixation, 888.3070, MNH, MNI, NKB

Predicate Devices:
- GSS Pedicle Screw System (K053573)
- Synthes Pangea System (K052123)
- INCOMPASS SPINAL FIXATION SYSTEM (K021564)

Device Description
Device Description: The AnyPlus Spinal Fixation System consists of various hooks, screws, rods and connectors and is intended to create a rigid spinal construct. A table of components can be found in Section 11.

Intended Use
The AnyPlus Spinal Fixation System includes components from GSS Pedicle Screw System previously cleared in K053573. These components will keep their original cleared trade name. A table of components can be found in Section 11 identified as GSS Pedicle Screw System 510(k): K053573.

The components are manufactured from Ti6Al4V ELI according to ISO 5832-3 and ASTM F-136. The screws are available from 4.0 to 10.5mm diameters with lengths ranging from 20 to 100mm (Length does not include the screw head).

Specialized instruments are available for the application and removal of the AnyPlus Spinal Fixation System. A table of components can be
Intended Use: AnyPlus Spinal Fixation System are non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2), a posterior hook fixation system (T1-L5), or as an anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. System components are to be used for immobilization and stabilization of the spine as an adjunct to fusion. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion.

Summary of Technical Characteristics

<table>
<thead>
<tr>
<th>Feature</th>
<th>AnyPlus Spinal Fixation System</th>
<th>GSS Pedicle Screw System</th>
<th>Synthes Pangea System</th>
<th>INCOMPASS SPINAL FIXATION SYSTEM</th>
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<tbody>
<tr>
<td>510(k) Number</td>
<td>K091717</td>
<td>K053573</td>
<td>K052123</td>
<td>K021564</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>GS MEDICAL CO., LTD.</td>
<td>GS MEDICAL CO., LTD.</td>
<td>SYNTHES (USA)</td>
<td>SPINAL CONCEPTS, INC</td>
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<tr>
<td>Classification # &amp; Product Code</td>
<td>888.3050, 888.3060, 888.3070</td>
<td>888.3070</td>
<td>888.3050</td>
<td>888.3060</td>
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<td>KWP, KWQ, MNH, MNI</td>
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<td>Intended Use</td>
<td>AnyPlus Spinal Fixation System are non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2), a posterior hook fixation system</td>
<td>The GSS Pedicle Screw System is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone grafting.</td>
<td>The Synthes USS (including the ClickX®, and USS VAS variable axis components, and Pangea™), ClickX® Monaxial, Dual-Opening and the Small Stature USS (which when intended for pedicle screw fixation from T1-S1, the InCompass Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients)</td>
<td>When intended for pedicle screw fixation from T1-S1, the InCompass Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients.</td>
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**Section 5.0: 510(k) Summary**
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<tr>
<td>(T1-L5), or as a anterolateral fixation system (T8-L5). Pedicle screw fixation is limited to skeletally mature patients. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann’s Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion.</td>
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<td>Submitter: GS Medical Co., Ltd.</td>
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<tr>
<td><strong>Premarket Notification:</strong> Traditional 510(k)</td>
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AnyPlus Spinal Fixation System  
Premarket Notification: Traditional 510(k)

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<tr>
<th>Material</th>
<th>Titanium Alloy (Ti-6Al-4V ELI)</th>
<th>Titanium Alloy (Ti-6Al-4V ELI)</th>
<th>Titanium Alloy</th>
<th>Titanium Alloy (Ti-6Al-4V ELI)</th>
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</thead>
</table>

and should be removed. In most cases, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. Any decision to remove the device must be made by the physician and patient, taking into consideration the patient's general medical condition and the potential risk to the patient for a second surgical procedure.
Dear Mr. Greenrose:

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 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” (21 CFR 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,

[Signature]
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

510(k) Number (if known): K091717

Device Name: AnyPlus Spinal Fixation System

Indications For Use:

AnyPlus Spinal Fixation System are non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2), a posterior hook fixation system (T1-L5), or as an anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. System components are to be used for immobilization and stabilization of the spine as an adjunct to fusion. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K091717