Dear Mr. Sowers:

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); 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure
Indications for Use

TiLock² Spinal System

Indications for Use (Describe)
The TiLock² Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease; spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).
DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:
The intent of this Special 510(k) is threefold:

1. To add the KWP product code to the system
2. Clarify the system classification is now Class II in accordance with Docket No. FDA-2014-N-1205
3. Add / revise system instrumentation

The Genesys Spine TiLock² Spinal System is offered in polyaxial screws (solid and cannulated) and monoaxial screws in various lengths and diameters, offset connectors, washers, hooks, rod-to-rod connectors, lock screws, crosslinks, and rods in various lengths and materials.
INDICATIONS FOR USE
The TiLock² Spinal System is intended to provide immobilization and stabilization of
spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of
the following acute and chronic instabilities or deformities of the thoracic, lumbar, and
sacral spine: degenerative disc disease; spondylolisthesis; fracture; dislocation; scoliosis;
kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

TECHNICAL CHARACTERISTICS
The Genesys Spine TiLock² Spinal System is comprised of polyaxial screws (solid and
cannulated) and monoaxial screws in various lengths and diameters, offset connectors,
washers, hooks, rod-to-rod connectors, lock screws, crosslinks, and rods in various
lengths. The TiLock² System only allows the placement of 5.5mm titanium or cobalt
chromium rods. The TiLock² cannulated polyaxial screws may be implanted via a
minimally invasive technique. Manual instrumentation for implantation of the system is
available for both conventional and minimally invasive procedures. The TiLock² tulips
are available in three (3) configurations: standard, break off and extended tab. The
extended tab tulips are only assembled utilizing cannulated screws, as it is intended to
facilitate screw insertion during minimally invasive procedures. The TiLock²
implantable components are manufactured from medical grade Ti-6Al-4V ELI titanium
alloy per ASTM F136 and cobalt-chromium-molybdenum alloy per ASTM F1537.

The Genesys Spine TiLock² Spinal System implants remain unchanged from their
previously cleared configuration outlined in K100757, K103034, and K152039. As such
no new testing or analysis is required. In addition, since all of the implants have been
previously cleared they do not present any new risks to mechanical strength or
performance. The devices in the TiLock² Spinal System are utilized in the same manner
as the predicate devices.

PERFORMANCE DATA
Not Required. There was no change to the cleared system implants or the manner in
which they are used. The instrument additions mimic previously cleared instruments
with minor alterations.

CONCLUSION
The technology and characteristics of the TiLock² Spinal System remains unchanged.
Laminar hooks were previously cleared per K152039. This submission adds the KWP
product code corresponding to spinal interlaminal fixation orthosis. The added system
instrumentation are all derivatives of previously cleared system devices and do not add
any new technology or novel characteristics. As a result, the modified TiLock² Spinal
System is considered substantially equivalent to the previous Genesys Spine TiLock /
TiLock² Systems (Genesys Spine - K100757 / K103671 / K152039) as well as the LANX
Spinal Fixation System (K122145).