Intelivation LLC
% Barry Sands
President
RQMIS, Inc.
110 Haverhill Road, Suite 524
Amesbury, Massachusetts 01913

August 19, 2021

Re: K212185
Trade/Device Name: Golden Isles Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: July 9, 2021
Received: July 13, 2021

Dear Barry Sands:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531 - 542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212185

Device Name
Golden Isles Pedicle Screw System

Indications for Use *(Describe)*
The Golden Isles Pedicle Screw System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the lumbar and/or sacral spine as follows:

The Golden Isles System is intended for posterior, non-cervical pedicle fixation in skeletally mature patients for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

In addition, when used as a pedicle screw fixation system, the Golden Isles Pedicle Screw System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint, (b) who are receiving fusions using autogenous bone graft only, (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below), and (d) who are having the device removed after the development of a solid fusion mass.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Intelivation Technologies Golden Isles Pedicle Screw System

I. Submitter

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Date Prepared: 08/11/2021

II. Subject Device

Trade/proprietary name of device:	Golden Isles Pedicle Screw System
Common or Usual Name:	Pedicle Screw System
Classification Name:	Thoracolumbosacral Pedicle Screw System
Regulation Number:	21 C.F.R. §888.3070
Classification:	Class II
Product code(s):	NKB

III. Predicate Devices

Preference Elite Pedicle Screw System (K162160)

IV. Device Description

The Golden Isles Pedicle Screw System is a spinal fixation system consisting of a variety of components including pedicle screws, modular head bodies, and various types and sizes of rods. The components are designed to be rigidly locked into a variety of configurations with each construct being appropriate for the individual patient. The

Golden Isles Pedicle Screw System implant components are fabricated from medical grade titanium alloy (Ti-6Al-4V) or cobalt chrome alloy (Co-28Cr-6Mo).

Indications for Use:

The Golden Isles Pedicle Screw System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the lumbar and/or sacral spine as follows:

The Golden Isles System is intended for posterior, non-cervical pedicle fixation in skeletally mature patients for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

In addition, when used as a pedicle screw fixation system, the Golden Isles Pedicle Screw System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint, (b) who are receiving fusions using autogenous bone graft only, (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below), and (d) who are having the device removed after the development of a solid fusion mass.

Technological Characteristics:

The Golden Isles Pedicle Screw System consists of a variety of components including screws, various types and sizes of rods, cross-connectors and accessories, as well as implant components. The components are designed to be rigidly locked into a variety of configurations with each construct being appropriate for the individual patient.

V. Comparison of Technological Characteristics with the Predicate Device:

The Golden Isles Pedicle Screw System is identical to the predicate device and is as safe and effective as the Preference Elite Pedicle Screw System. The Golden Isles Pedicle Screw System has the same intended/indication for use, technological characteristics, and principles of operation as its predicate device. There are no technological differences between the Golden Isles Pedicle Screw System and its predicate device resulting in no new issues of safety or effectiveness. Thus, the Golden Isles Pedicle Screw System is identical to predicate device.

VI. Performance Data

The subject and predicate devices are identical and therefore, no performance testing is

required: This submission is only transferring the name of a system that has already been cleared under K162160. No testing is required.

VII. Conclusion

The Golden Isles Pedicle Screw System and the primary predicate, Preference Elite Pedicle Screw System have the same intended use and identical indications, technological characteristics and principles of operation. There are no technological differences between the Golden Isles Pedicle Screw System and its predicate. Hence the Golden Isles Pedicle Screw System is substantially equivalent to the primary predicate.