December 6, 2024

GS Medical Co. Ltd.
Barry Sands
90, Osongsaengmyeong 4-ro, Osong-eup,
Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do
Korea, South

Re: K243073
Trade/Device Name: AnyPlus Navigated Instruments System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 27, 2024
Received: September 27, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243073

Device Name
AnyPlus Navigated Instruments System

Indications for Use *(Describe)*
The AnyPlus Navigated Instrument System is indicated for the preparation and placement of the Poly-Axial Screws of the AnyPlus Spinal Fixation System during a navigated thoracolumbar fusion procedure to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. This system is intended to be used in conjunction with the Medtronic StealthStation® System which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The use of the AnyPlus Navigated Instrument system is limited to use only with the AnyPlus Spinal Fixation System.

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.

510(K) SUMMARY

SUBJECT DEVICE: GS MEDICAL'S ANYPLUS® NAVIGATED INSTRUMENT SYSTEM

1. SUBMITTER'S CONTACT INFORMATION

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Date Prepared	**September 26, 2024**

2. SUBJECT DEVICE

Trade/Proprietary Name of Device:	Anyplus Navigated Instruments System
Common Or Usual Name:	Stereotaxic Instrument, Navigated Screwdriver, Tap
Classification Name:	Stereotaxic Instrument
Regulation Number:	21 CFR 882.4560
Classification:	Class II
Product Code:	OLO

3. PREDICATE DEVICE

Trade/Proprietary Name of Device:	Anyplus Spinal Fixation System
510(k) number:	K091717
Common Or Usual Name:	Pedicle Screw System
Classification Name:	Thoracolumbosacral Pedicle Screw System
Regulation Number:	21 CFR 888.3070
Classification:	Class II
Product Code:	NKB, KWP, KWQ, MNH, MNI

4. ADDITIONAL PREDICATE

Trade/Proprietary Name of Device:	Navigated CD Horizon Solera Screwdrivers and Taps
510(k) number	K140454
Common Or Usual Name:	Stereotaxic Instrument
Classification Name:	Stereotaxic Instrument
Regulation Number:	21 CFR 882.4560
Classification:	Class II
Product Code:	OLO

5. INDICATIONS FOR USE

The AnyPlus Navigated Instrument System is indicated for the preparation and placement of the Poly-Axial Screws of the AnyPlus Spinal Fixation System during a navigated thoracolumbar fusion procedure to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. This system is intended to be used in conjunction with the Medtronic StealthStation® System which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The use of the AnyPlus Navigated Instrument system is limited to use only with the AnyPlus Spinal Fixation System.

6. DEVICE DESCRIPTION

The subject device, AnyPlus Navigated Instrument System, includes Taps and a Driver that are compatible with the Medtronic StealthStation® S7 Navigation System. The subject, AnyPlus Navigated Instruments (Taps and Driver), is used to place the GS Medical's AnyPlus Spinal Fixation pedicle screws (Poly-Axial Screws) during a navigated thoracolumbar fusion procedure. These instruments include a regular driver for AnyPlus pedicle screws and multiple taps ranging from 4.5mm to 8.5mm in diameter, increasing by increments of 0.5mm.

These Navigated Instruments are supplied non-sterile, reusable, and fabricated from UNS S45500 Precipitation-Hardened Stainless Steel in accordance with ASTM F899. The material and manufacturing process of the subject device, AnyPlus Navigated Instruments, are identical to the primary predicate (Anyplus Spinal Fixation Systems Drivers and taps, K091717).

7. Technological Characteristics comparison:

The Subject Device: AnyPlus Navigated Instrument system and the Primary Predicate: AnyPlus Spinal Fixation System (K091717), have identical material, the same technological characteristics, and the principle of operation (to implant an AnyPlus Screw).The Subject Device: AnyPlus Navigated Instruments, and the Additional Predicate: Navigated CD Horizon® Solera® Screwdrivers and Taps (K140454), have identical indications for use/intended use.

Both the subject device and additional predicate's Taps and driver are intended to place the pedicle screws during the spinal surgery with the help of the Medtronic StealthStation® system. Both the subject device and additional predicate Taps and driver have equivalent critical lengths with a +/-0.15mm difference in tolerance. This minor difference between the subject device and the additional predicate instruments' critical length does not raise new questions of safety and effectiveness since the performance testing proves that the subject device Taps and driver successfully register and place the AnyPlus pedicle screws with the help of Medtronic Stealth Station System as same as the additional predicate.

8. PERFORMANCE DATA

Both the subject device AnyPlus Navigated Instrument system (Driver and Tap) and the additional predicate device Navigated CD HORIZON® SOLERA® (Driver and Tap) passed recognition and location testing with the Medtronic StealthStation® navigation system. Subject device and additional predicate Driver and Tap were compared for dimensional accuracy, and the critical length are within the tolerance limit. The subject device is equivalent to the predicate device in use and performance.

9. CONCLUSION

- The subject device, AnyPlus Navigated Instrument, and the additional predicate, the Navigated CD Horizon Solera Screwdrivers and Taps (K140454), have identical indications for use/intended use.
- The subject device and the primary predicate instruments (i.e., Driver and Taps) have identical material, the same technological characteristics, and the principle of operation.
- The performance of the subject device (i.e., dimensional accuracy, verification, and compatibility of the subject Taps and Drivers to the Medtronic Stealth Station) was equivalent to the additional predicate. Acceptable performance test results demonstrate that the subject device is as safe and effective as its primary and additional predicate.