April 2, 2021

DeGen Medical
% Linda Braddon
President/CEO
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K203816
Trade/Device Name: DeGen Navigated Instrumentation
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 11, 2021
Received: March 15, 2021

Dear Linda Braddon:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203816

Device Name
DeGen Medical Navigated Instrumentation

Indications for Use *(Describe)*
The DeGen Medical Navigated Instrumentation is intended to be used during the preparation and placement of DeGen Medical F1 MPS and E3 MIS screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. DeGen Medical Navigated Instrumentation is specifically designed for use 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary: DeGen Medical Navigated Instrumentation
K203816

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the DeGen Navigated Instrument is provided below.

Date Prepared	3/10/2021
Sponsor	DeGen Medical 1321-C North Cashua Drive Florence, SC 29501 Phone 877-240-7838 Fax 843-407-0545 FDA Registration: 3010663372
510(k) Contact	Secure BioMed Evaluations Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	DeGen Medical Navigated Instrumentation
Common Name	Navigated Instruments
Classification Name	Sterotaxic Instrument
Code– Classification	OLO 21 CFR 882.4560 : Class II
Primary Predicate	K140454 Medtronic Navigated CD Horizon Solera Screwdriver / Taps
Additional Predicate	K172166 Astura Olympic Navigated Instruments
Device Description	The DeGen Navigated Instrumentation is nonsterile, reusable drivers that are intended to be used with the Medtronic StealthStation® Application 1.2.0 (1.2.0-20) and are manufactured from stainless steel per ASTM F899.
Materials	Stainless Steel per ASTM F899
Indications for Use	The DeGen Medical Navigated Instrumentation is intended to be used during the preparation and placement of DeGen Medical F1 MPS and E3 MIS screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. DeGen Medical Navigated Instrumentation is specifically designed for use 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.

510(k) Summary: DeGen Medical Navigated Instrumentation
K203816

Technological Characteristics	The technological design features of the subject system were compared to the predicate in intended use, indications for use, design, function and technology and it was demonstrated that they are substantially equivalent.
Non-Clinical Test Summary	The following analyses were conducted: • Dimensional analysis compared to predicate • Anatomical simulated use and navigation accuracy The results of these evaluations indicate the subject device is equivalent to the predicate device.
Conclusions	The comparison of technological characteristics and non-clinical performance data demonstrates that the Subject Device is as safe and effective when compared to Predicate Devices that are currently marketed for the same intended use.