Globus Medical Inc.
Kelly Baker
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

January 29, 2019

Re: K182000
Trade/Device Name: AQrate Robotic Assistance System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 8, 2019
Received: January 9, 2019

Dear Kelly Baker:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2019.01.29 15:52:33 -05'00'

For:
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182000

Device Name

AQrate Robotic Assistance System

Indications for Use *(Describe)*

The AQrate™ Robotic Assistance System is intended to be used for spatial positioning and orientation of an instrument holder or instrument guide to be used by surgeons to guide instruments during surgery in either open or percutaneous procedures. The instruments and instrument guides are 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 a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. The system is indicated for the placement of spinal screws.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: AQrate™ Robotic Assistance System

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared: January 8, 2019

Device Name: AQrate™ Robotic Assistance System

Common Name: Robotic Assistance System

Classification: Per 21 CFR as follows:
§882.4560 Stereotaxic instrument
Product Code(s): OLO
Regulatory Class: II

Primary Predicate: ExcelsiusGPS™ (K171651)

Additional Predicate: Globus Navigation Instruments (K180690)

Reference: Medtronic StealthStation (K133444)

Purpose:
The purpose of this submission is to request clearance of the AQrate™ System.

Device Description:
The AQrate™ Robotic Assistance System is a medical robotic system with a robotic arm fixed to a mobile cart, hardware, and software. The system allows for accurate positioning of surgical instruments and screws during spinal surgery with the use of a robotic arm. The instruments may be navigated or tracked relative to the patient's anatomy on reconstructed images using the Medtronic StealthStation® System.

Indications for Use:
The AQrate™ Robotic Assistance System is intended to be used for spatial positioning and orientation of an instrument holder or instrument guide to be used by surgeons to guide instruments during surgery in either open or percutaneous procedures. The instruments and instrument guides are 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 a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. The system is indicated for the placement of spinal screws.

Technological Characteristics:
AQrate™ has similar technological characteristics to the predicate devices including the main system components, workflow, user interface, software features, and design. The AQrate™ System is comparable to the predicates in terms of intended use, fundamental scientific technology, technological characteristics and principle of operation. Biocompatibility of patient-contacting materials was demonstrated by using materials that meet applicable standards or are used in 510(k) cleared devices.

Performance Testing:
Verification testing was conducted on AQrate™ to confirm that the device meets performance requirements under the indications for use and to ensure safety and efficacy of the system:

- Non-clinical system, software, and instrument verification
- Surgical simulations conducted on phantom models
- Compliance conformity assessments per:
  - IEC 60601-1 Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
  - IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2014
  - IEC 60601-1-6 Medical Electrical Equipment - Part 1-6, General Requirements for Basic Safety and Essential Performance – Usability 2010 + A1:2013

Software Verification and Validation Testing
Software validation and verification testing was performed in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005) and IEC 62304:2006 Medical Device Software – Software life cycle processes.

Basis of Substantial Equivalence:
AQrate™ has been found to be substantially equivalent to the predicate devices with respect to technological characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices.