October 26, 2026

Blue Ortho
Matthieu Coic
Quality and Regulatory Director
22, Chemin Du Vieux Chêne
Meylan, 38240
France

Re: K262567
Trade/Device Name: GPS Ankle
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 24, 2026
Received: July 24, 2026

Dear Matthieu Coic:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262567

Please provide the device trade name(s).

GPS Ankle

Please provide your Indications for Use below.

GPS Ankle software is intended for use during preoperative planning and during orthopedic surgery with the Advita GPS System to aid the surgeon in locating anatomical structures and aligning the endoprosthesis with the anatomical structures provided that the required anatomical landmarks can be identified on the patient's preoperative CT scan.

GPS Ankle – Planning software is specifically indicated for pre-operative planning of Total Ankle Arthroplasty using the Vantage ankle system. It allows to visualize and measure anatomical structures in order to select and place the Tibial and Talar components and display resulting measurements.

GPS Ankle - Navigation software is specifically indicated for Total Ankle Arthroplasty using the Vantage ankle system and the Advita GPS System to aid the surgeon in locating anatomical structures and align the tibia and talar components with the anatomical structures.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #: K262567

510(k) Summary

Prepared on: 2026-07-24

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Blue Ortho
Applicant Address	22 Chemin du Vieux Chêne Meylan 38240 France
Applicant Contact Telephone	+33458003525
Applicant Contact	Mr. Matthieu Coic
Applicant Contact Email	matthieu.coic@blue-ortho.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	GPS Ankle
Common Name	Stereotaxic instrument
Classification Name	Orthopedic Stereotaxic Instrument
Regulation Number	882.4560
Product Code(s)	OLO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K232521	ExactechGPS Total Ankle Application	OLO
K241999	Prophecy® Surgical Planning 3D Viewer	HSN

Device Description Summary

21 CFR 807.92(a)(4)

The Advita GPS System is an image-guided surgery, or navigation, system intended to be used during orthopedic surgical procedures to intraoperatively assist surgeons during arthroplasty. The Advita GPS system enables surgeons to acquire intraoperative data by computing and displaying information such as distances, angles, and placement of prosthetic components in order to identify and characterize bone preparation necessary to achieve surgical goals.

Software applications allow surgeons to view real-time data describing patient anatomy and instrument position while preparing patient bone during stereotaxic surgery. The proposed GPS Ankle software application is a medical device designed to preoperatively plan and intraoperatively assist surgeons during ankle arthroplasty.

The Advita GPS system works with Advita GPS trackers that communicate intraoperative data to the Advita GPS station to provide surgeons with real-time information on the positions of patient anatomical structures and of instrumentation used to prepare patient bone during stereotaxic surgery.

The proposed modifications do not change the Advita GPS System general intended use, general design features, or basic fundamental scientific technology.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

GPS Ankle software is intended for use during preoperative planning and during orthopedic surgery with the Advita GPS System to aid the surgeon in locating anatomical structures and aligning the endoprosthesis with the anatomical structures provided that the required

anatomical landmarks can be identified on the patient's preoperative CT scan.

GPS Ankle – Planning software is specifically indicated for pre-operative planning of Total Ankle Arthroplasty using the Vantage ankle system. It allows to visualize and measure anatomical structures in order to select and place the Tibial and Talar components and display resulting measurements.

GPS Ankle - Navigation software is specifically indicated for Total Ankle Arthroplasty using the Vantage ankle system and the Advita GPS System to aid the surgeon in locating anatomical structures and align the tibia and talar components with the anatomical structures.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The GPS Ankle software is an evolution of the predicate device, and includes the following new feature compared to the primary predicate:
- A preoperative planning feature that enables surgeons to plan a surgical intervention ahead of the surgery, by evaluating implant size, type, and positioning using reconstructed patient bone models in a virtual environment.
This pre-operative planning feature does not affect or change the intended use.

The secondary predicate device has been selected to support preoperative planning functionality only, not to redefine the whole device comparison.

Technological Comparison

21 CFR 807.92(a)(6)

Proposed device GPS Ankle software and primary predicate device ExactechGPS Total Ankle Application (now Advita GPS) are similar regarding the overall intended use, navigation workflow, the platform and the basic fundamental technology:
- They have the same Intended use
- They are used at the same sites in the body with similar hardware system, instruments, and computer systems.
- Intraoperative actions and sequence of use are similar for the proposed device and cited predicate.

The secondary predicate device is used to support the specific preoperative planning of ankle arthroplasty, with possibility to select implant size, orientation, and alignment.

Both the subject and the two selected predicate devices are similar regarding:
- Clinical purpose (ankle arthroplasty) and functional and performance indication
- Target population
- User profile
- Clinical context (preoperative step, intraoperative step to perform ankle arthroplasty)

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Testing information demonstrating safety and effectiveness of the GPS Ankle software is supported by testing that was conducted in-house. This submission includes or references the following non-clinical testing:
- Software verification testing to ensure all design outputs meet all specified requirements
- Software validation testing in simulated use environments with surgeon users and cadaver specimens to ensure software specifications conform to user needs and intended use.