December 16, 2022

Taiwan Main Orthopaedic Biotechnology Co., Ltd.
Min-Liang Wang, CEO
1F., No. 46, Keya Rd., Daya Dist.
Taichung City, 42881 Tw

Re: K220554
Trade/Device Name: Caduceus S
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 30, 2022
Received: November 30, 2022

Dear Min-Liang Wang:

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,

Jesse Muir -S

For; 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)*

K220554

Device Name
Caduceus S

Indications for Use *(Describe)*

Caduceus S is intended as an intraoperative guidance system to enable minimally invasive surgery. Intraoperatively registered surgical Instruments are tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or intraoperative 2D or 3D image data.

Caduceus S enables image-guide navigation of medical image data, which can either be acquired preoperatively CT or intraoperatively C-arm by an appropriate image acquisition system.

Caduceus S offers pedicle screw implant size planning and navigation on rigid bone structures with intraoperatively registered surgical Instruments.

Caduceus S is indicated for L5~T6 spine surgery where reference to a rigid anatomical structure can be identified relative to the acquired patient imagery (CT or C-arm).

The headset (Surglasses) of the Caduceus S system is an optional heads up display that projects the 2D stereotaxic screens of the system's display.

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."

K220554

510(k) SUMMARY

5.1 Type of Submission: Traditional

5.2 Date of Summary: February 25, 2022

5.3 Submitter:

Address:	Taiwan Main Orthopaedic Biotechnology Co., Ltd. 1F., No. 46, Keya Rd., Daya Dist., Taichung City 428, Taiwan (R.O.C.)
Phone:	+886-4-3707-3159
Fax:	+886-4-2565-3330
Contact:	Jacky Fan (Regulatory Affair)

5.4 Identification of the Device:

Proprietary/Trade name:	Caduceus S
Classification Product Code:	OLO
Regulation Number:	882.4560
Regulation Description:	Stereotaxic instrument
Review Panel:	Orthopedic
Device Class:	II
Basis for the Submission:	New Device

5.5 Identification of the Predicate Device:

Predicate Device Name:	Spine & Trauma Navigation
Submitter:	Brainlab AG
Classification Product Code:	OLO
Regulation number:	882.4560
Device Class:	II
510(k) Number:	K183605

5.6 Identification of the Reference Device:

Reference Device Name:	xvision Spine system (XVS)
Submitter:	Augmedics Ltd.
Classification Product Code:	OLO

Regulation number:	882.4560
Device Class:	II
510(k) Number:	K190929

5.7 Indications for Use

Caduceus S is intended as an intraoperative guidance system to enable minimally invasive surgery. Intraoperatively registered surgical Instruments are tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or intraoperative 2D or 3D image data.

Caduceus S enables image-guide navigation of medical image data, which can either be acquired preoperatively CT or intraoperatively C-arm by an appropriate image acquisition system.

Caduceus S offers pedicle screw implant size planning and navigation on rigid bone structures with intraoperatively registered surgical Instruments.

Caduceus S is indicated for L5~T6 spine surgery where reference to a rigid anatomical structure can be identified relative to the acquired patient imagery (CT or C-arm).
The headset (Surglasses) of the Caduceus S system is an optional heads up display that projects the 2D stereotaxic screens of the system’s display.

5.8 Device Description

Caduceus S surgical navigation system is an image guidance system, which is composed of Navi Tracker, Surglasses, other hardware (Navigation Cart with an arm, Touch Screen, Router, Control System, Connection System), disposable tools (Disposable Passive Sphere, Straight Guide Pin, Navi Clamp Kit, Instrument Adapter Type A&B, Calibration Plate, Registration Kit, Correction Tool), reusable tools (Calibration Board, Instrument Holder), and Spine Navigation Software. Caduceus S is an optical tracking and guiding system for spine surgery. It can track the marks on the surgical instruments and patient's anatomical structure with marks, and register with the preoperative or intraoperative images of the patients. During the surgery, it can be displayed on the Touch Screen and the head mounted display Surglasses to provide the navigation for the surgical instruments.

5.9 Substantial Equivalence Determination

Equivalence, same and difference among the subject, predicate and reference devices are cited as below.

Item	Subject Device	Predicate Device	Reference Device	Substantial Equivalence Determination
Proprietary Name	Caduceus S	Spine & Trauma Navigation	xvision Spine system (XVS)	
510(k) No.		K183605	K190929	
Indications for Use	Caduceus S is intended as an intraoperative guidance system to enable minimally invasive surgery. Intraoperatively registered surgical Instruments are tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or intraoperative 2D or 3D image data. Caduceus S enables image-guide navigation of medical image data, which can either be acquired preoperatively CT or intraoperatively C-arm by an appropriate image acquisition system. Caduceus S offers pedicle screw implant size planning and navigation on rigid bone structures with	Spine & Trauma 3D is intended as an intraoperative image-guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or Intraoperative 2D or 3D image data. Spine & Trauma 3D enables computer-assisted navigation of medical image data, which can either be acquired preoperatively or inter-operatively by an appropriate image acquisition system. The software offers screw implant size planning and navigation on rigid bone structures with precalibrated and	The xvision Spine System, with xvision Spine System Software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous spine procedures. Their use 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 the spine, can be identified relative to CT imagery of the anatomy. This can include the spinal implant procedures, such as Posterior Pedicle Screw Placement in the thoracic and sacro-lumbar region. The Headset of the xvision Spine	***Equivalent*** Both the subject and predicate devices are an intraoperative image-guided localization system to enable minimally invasive surgery, and the subject device is focus on spine surgery. Both the subject and reference devices display the image by a headset and a screen. Although there are some technical differences among these devices, the subject device is tested and

	intraoperatively registered surgical Instruments. Caduceus S is indicated for L5~T6 spine surgery where reference to a rigid anatomical structure can be identified relative to the acquired patient imagery (CT or C-arm). The headset (Surglasses) of the Caduceus S system is an optional heads up display that projects the 2D stereotaxic screens of the system's display.	additional individually-calibrated surgical tools. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.	System displays 2D stereotaxic screens and a virtual anatomy screen. The stereotaxic screen is indicated for correlating the tracked instrument location to the registered patient imagery. The virtual screen is indicated for displaying the virtual instrument location in relation to the virtual anatomy to assist in percutaneous visualization and trajectory planning. The virtual display should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed stereotaxic information.	validated so that the difference does not raise new issues of SE.
Type of Use	Prescription Use	Prescription Use	Prescription Use	***Same***
Use Environment	Operating Room	Operating Room	Operating Room	***Same***
Main Component	• Platform including cart, computer, monitor and tracking cameras • Headset with near eye see-through	• Platform including cart, computer, monitor and tracking cameras • Software application	• Headset with near eye see-through display and tracking camera	***Equivalent*** The subject device is composed of headset as the

	display • Navi tracker • Software application • Reflective markers – Spheres • Instrument universal adaptors	• Reflective markers – Spheres • Accessories (Instrument adaptors, referencing system)	• Software application • Reflective markers – Flat • Instrument universal adaptors • Reference point	reference device does, and the rest components are similar with that of the predicate device. Although the main component is slightly different among these devices, the subject device is tested and validated so that the difference does not raise new issues of SE.
Modes of Operation	• Patient Preparation • System Set-up • Intraoperative scan • Scan Import • Planning • Patient Registration • Navigation	• Patient Preparation • System Set-up • Intraoperative scan • Scan Import • Planning • Patient Registration • Navigation	• Patient Preparation • System Set-up • Intraoperative scan • Scan Import • Patient Registration • Navigation	***Equivalent*** The modes of operation are the same between subject and predicate devices.
Localization Technology	Optical	Optical	Optical	***Same***
Optical Tracker	Two infrared cameras, positioned 1.3 ~ 2 m away from tracked objects	Two infrared cameras, positioned 2 ~ 3 m away from tracked objects	Single infrared camera, positioned 0.5m above tracked objects	***Equivalent*** The number of tracking cameras is the same between subject and predicate

				devices. Although the positioning distance is slightly different among these devices, the subject device is tested and validated so that the difference does not raise new issues of SE.
Tracking of Rotational Motion	6 degrees of freedom (DOF)	6 degrees of freedom (DOF)	6 degrees of freedom (DOF)	***Same***
Tracking Algorithm	Triangulation	Triangulation	Perspective N-point	***Equivalent*** The tracking algorithm is the same between subject and predicate devices, and it is compared on the headset between subject and reference devices. The difference does not raise new issues of SE.
System Accuracy Requirement	System Level Accuracy with a mean positional error of 2.0 mm and mean trajectory error of 2°	System Level Accuracy with a mean positional error of 2.0 mm and mean trajectory error of 2°	System Level Accuracy with a mean positional error of 2.0 mm and mean trajectory error of 2°	***Same***
Imaging Modality	X-Ray Based Imaging	X-Ray Based Imaging	X-Ray Based Imaging	***Same***

Item	Subject Device	Predicate Device	Reference Device	Substantial Equivalence Determination
Proprietary Name	Caduceus S	Spine & Trauma Navigation	xvision Spine system (XVS)	
510(k) No.		K183605	K190929	
Display Features	2D images: axial and sagittal 3D model Trajectories Trajectory guidance Instrument's tip view 3D transparent 3D OFF (only 2D) 3D follow instrument movement	Look Sideways 3D Anatomic Orthogonal Trajectory 1 and 2 Trajectory Guidance Look Ahead Probe's Eye AP and Lateral Synthetic AP and Lateral Maximum Intensity Projection Video Input	2D images: axial and sagittal 3D model Trajectories Trajectory guidance Instrument's tip view 3D transparent 3D OFF (only 2D) 3D follow instrument movement	***Equivalent*** The display features are the same between subject and reference devices.
Software Interface (GUI)	Black and gray style with procedure task overview in a menu. Software controls for images, instrument and planned trajectory management are contained in a left side bar.	Black and gray style with procedure task overview in left menu option and next/back task flow at bottom of the screen. Software controls for images, planning and instrument management are contained in a right side bar.	Black and blue style with procedure task overview in a menu and next/back task flow. Software controls for images, instrument and planned trajectory management.	***Equivalent*** Although the design of software interface is slightly different among these devices, the subject device is tested and validated so that the difference does not raise new issues of SE.
Display and	Augmented Reality using near eye	Data displayed on a monitor	Augmented Reality using near eye	***Equivalent***

Optics Technology	see-through display; data displayed on patient's anatomy.		see-through display; data displayed on patient's anatomy.	The display technology is the same between subject and reference devices.
Frame rate of displayed images	60 fps	(not revealed)	60 fps	***Equivalent*** The frame rate is the same between subject and reference devices.
Headset power source	Li-ion rechargeable battery	(no headset)	Li-ion rechargeable battery	***Equivalent*** The frame rate is the same between subject and reference devices.
Communication between Scanner and platform/ computer	CD、DVD、USB DCIOM Import	Network Connectivity CD、DVD、USB DCIOM Import DCIOM Export	USB & LAN connectivity using DICOM	***Equivalent*** Although the communication way between scanner and computer is slightly different among these devices, the subject device is tested and validated so that the difference does not raise new issues of SE.
Communication between Headset and computer	Wireless, encrypted	(no headset)	Wireless, encrypted	***Equivalent*** The communication way between headset and

				computer is the same between subject and reference devices.
Applications	C-arm Imaging System CT Imaging System	(not revealed)	O-arm Imaging System Ziehm Vision FD Vario 3D C-Arm and RFD 3D Siemens CIOS SPin Airo system by Brainlab	***Equivalent*** Although the application is slightly different among these devices, the subject device is tested and validated so that the difference does not raise new issues of SE.

5.10 Similarity and Difference

The Caduceus S has been compared with predicate device "Spine & Trauma Navigation" and reference device "xvision Spine system". The subject device has same intended use, principle of operation and similar technological characteristics as the predicate and reference devices. The subject device has undergone safety and performance tests, and the results complied with the test requests.

Although there are some different specifications between these devices, the performance test has been completed to demonstrate that the differences between these parameters would not impact the safety and effectiveness of the subject device. Therefore, the difference among the subject, predicate and reference devices did not raise any new issue of substantial equivalence. The subject device is substantially equivalent to the predicate and reference devices in intended use, design and performance claims.

5.11 Summary of Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, Caduceus S.

Test	Conclusion	Main Reference
General design requirements and risk analysis	Verification of general design requirements is successful, and risk control measures are effective and mitigate the associated risks.	ISO 14971
Sterilization Validation for EO sterile surgical instruments	The testing of device safety for sterilization as well as validation is successful, and all requirements are met.	ISO 11135; ISO 10993-7; ISO 11737-1; ISO 11737-2
Reliability Test for electrical hardware	The testing of general device function in critical environment is successful, and all requirements are met.	N/A
Shelf Life Test for EO sterile surgical instruments	The testing of device safety for shelf life of sterile package is successful, and all requirements are met.	ASTM F1980; ASTM F1886 / F1886M; ASTM F1140 / F1140M; ASTM F1929; ASTM F88 / F88M
Biocompatibility Tests for surgical instruments	The testing of device safety for biocompatibility is successful, and all requirements are met.	ISO 10993-1 and the subsequent standards; FDA Guidance for Use of International Standard ISO 10993-1.
Software Validation	The testing of software validation is successful, including unit and integration tests, and all requirements are met.	IEC 62304; FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
Cybersecurity Evaluation	The evaluation of device demonstrates the positive cybersecurity under the expected using environment, and all requirements are met.	FDA Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

Test	Conclusion	Main Reference
Electromagnetic Compatibility and Electrical Safety Tests for electrical hardware	The testing of device EMC & Electrical safety is successful, and all requirements are met.	IEC / EN 60601-1; IEC / EN 60601-1-2; FDA Guidance for Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices.
Wireless Coexistence Evaluation	The evaluation of device demonstrates the positive wireless coexistence under the expected using environment, and all requirements are met.	AAMI TIR 69; ANSI IEEE C63.27; FDA Guidance for Radio Frequency Wireless Technology in Medical Devices.
Performance on the head mounted display	The testing of device intended performance is successful, and all requirements are met.	Field of View(FOV),resolution, luminance, transmission, distortion, contrast ratio, latency
System's accuracy Performance and Usability of device intended use	The System Level Accuracy was also validated in a cadaver study, in which pedicle screws were positioned percutaneously in L5~T6 spine, using the Navi Clamp Kit as the rigid reference point. The positional error was calculated as the difference between the actual screw tip position, derived from the post-op scan, and its virtual tip, as recorded by the Caduceus S system. The trajectory error was calculated as the difference between the screw orientation and its recorded virtual trajectory. An overall mean positional error of 1.91mm (99% UBL*= 2.07mm) and angular error of 1.59 (99% UBL*=1.71) was measured under CT mode and overall mean positional error of 1.80mm (99% UBL*=2.06mm) and angular error of 1.65 (99% UBL*=1.80) was measured under C-arm mode. Thus, the system has demonstrated performance in 3D positional accuracy with a mean error statistically	IEC 63145-20-20; ASTM F2554; IEC 62366-1; FDA Guidance for Applying Human Factors and Usability Engineering to Medical Devices.

	significantly lower than 3mm and in trajectory angle accuracy with a mean error statistically significantly lower than 3 degrees, both in phantom and cadaver studies.	

All the test results demonstrate Caduceus S meets the requirements of its pre-defined acceptance criteria and intended use, and performs as safely and effectively as predicate and reference devices.

5.12 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

5.13 Conclusion

After comparing the devices and analyzing non-clinical safety & performance testing data, it can be concluded that the Caduceus S is substantially equivalent to the predicate and reference devices.