October 30, 2024

Taiwan Main Orthopaedic Biotechnology Co., Ltd.
Jacky Fan
Regulatory Affairs Manager
2F., No. 41, Keya Rd., Daya Dist
Taichung City, 428015
Taiwan

Re: K242271
Trade/Device Name: Caduceus S
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: SBF
Dated: May 2, 2024
Received: August 1, 2024

Dear Jacky Fan:

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,

Tejen D. Soni -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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242271

Device Name

Caduceus S

Indications for Use *(Describe)*

Caduceus S is intended as an aid for precisely locating anatomical structures in percutaneous spine procedures. It is indicated for medical conditions in which the use of stereotactic surgery may be appropriate, when reference to a rigid anatomical structure, such as the spine or pelvis, can be identified relative to CT or 2D/3D C-arm images of the anatomy. This can include the spinal implant procedures, such as Posterior Pedicle Screw Placement in the thoracic and lumbosacral spine. Caduceus S offers pedicle screw implant size planning and navigation on rigid bone structures with intraoperatively registered surgical Instruments. The Headset of the Caduceus S displays 2D stereotaxic screens and a 3D anatomy model (floating). The displayed stereotaxic screens are indicated for correlating the tracked instrument location to the patient registered imagery to assist in percutaneous visualization and trajectory planning.

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) #: K242271

510(k) Summary

Prepared on: 2024-08-01

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Taiwan Main Orthopaedic Biotechnology Co., Ltd.
Applicant Address	2F., No. 41, Keya Rd., Daya Dist., Taichung City 428015, Taiwan (R.O.C.) Taichung City 428015 Taiwan
Applicant Contact Telephone	+886-4-25652818
Applicant Contact	Mr. Jacky Fan
Applicant Contact Email	tbk.jacky@surglasses.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Caduceus S
Common Name	Stereotaxic instrument
Classification Name	Orthopedic Stereotaxic Instrument
Regulation Number	882.4560
Product Code(s)	SBF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K183605	Spine & Trauma Navigation	OLO

Device Description Summary

21 CFR 807.92(a)(4)

The Caduceus S system is an image-guided navigation system that is designed to assist surgeons in placing pedicle screws accurately, during percutaneous computer-assisted spinal surgery. The system consists of a dedicated software, Navigation Cart, Navi Tracker, Headset, Minimally Invasive Spine Surgery Instruments, Disposable Passive Spheres, and other disposable surgical consumables. It uses optical tracking technology and displays to the surgeon the location of the tracked surgical instruments relative to the acquired intraoperative patient's scan, onto the surgical field. The 2D scanned data and 3D reconstructed model, along with tracking information, are projected to the surgeons' eyes using a transparent near-eye-display Headset, allowing the surgeon to both look at the patient and the navigation data at the same time.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Caduceus S is intended as an aid for precisely locating anatomical structures in percutaneous spine procedures. It is indicated for medical conditions in which the use of stereotactic surgery may be appropriate, when reference to a rigid anatomical structure, such as the spine or pelvis, can be identified relative to CT or 2D/3D C-arm images of the anatomy. This can include the spinal implant procedures, such as Posterior Pedicle Screw Placement in the thoracic and lumbosacral spine. Caduceus S offers pedicle screw implant size planning and navigation on rigid bone structures with intraoperatively registered surgical Instruments. The Headset of the Caduceus S displays 2D stereotaxic screens and a 3D anatomy model (floating). The displayed stereotaxic screens are indicated for correlating the tracked instrument location to the patient registered imagery to assist in percutaneous visualization and trajectory planning

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device expanded indication for use for placing screws in additional spine segments.

This change does not alter the intended use of the device for its use as an aid in localization during spine surgery. Therefore,Caduceus S System is substantially equivalent in terms of intended use / indications for use.

Technological Comparison 21 CFR 807.92(a)(6)

The modified Caduceus S System is similar in its technological features to its predicate device, the cleared Caduceus S System. Both systems include very similar hardware and software components, with the following basic components: software, Headset with optical tracking camera, Disposable Passive Spheres, rigid reference point, and Instrument universal adaptors. The Headset in both systems is positioned on the surgeon's head and is designed to provide 2D and stereoscopic 3D augmented reality (AR) display with overlaid navigation information, onto patient's anatomy. The software in both systems is designed for real time calculation and display of the spatial position of the tip of the surgical instruments relative to patient's anatomy. Although there should be some different specifications among these devices, the tests performed on subject device demonstrate equivalent safety and effectiveness.".Both systems follow similar fundamental principles of operation.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following testing was conducted to evaluate the device:

• Performance of the Headset display was demonstrated by verifying the following elements:
Resolution, luminance, transmission, distortion, contrast ratio and latency.

•Electrical safety was tested in accordance with IEC 60601-1:2005+A1:2012+A2:2020 and EN 60601-1:2006+A11:2011+A1:2013 +A12:2014+A2:2021 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

• Electromagnetic Compatibility (EMC) was tested in accordance with IEC 60601-1-2:2014+AMD1:2020 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

• Sterilization validation for the single use components was conducted in accordance with the ANSI AAMI ISO 11135:2014/A1:2018. Additionally, shelf life and packaging testing were performed to support the labeled shelf life. All tests were successfully completed.

• Cleaning and sterilization process of the reusable instruments was validated to SAL 10-6. For steam sterilization, in compliance with the half-cycle validation approach outlined in ISO 17665-1, in accordance with the requirements of ISO 17664 and FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling".

• Biological evaluation was provided in order to confirm that the patient-contacting materials do not introduce new risks. The modified instruments are still covered by the testing done according to ISO 10993 series.

•Repeatability and accuracy were tested according to ASTM F2554.

•The system's accuracy was validated in three cadaver studies, in which screws were positioned in thoracic and lumbosacral spine. The positional and trajectory errors were calculated as the difference between the actual and virtual screw tip position, and the difference between the screw orientation and its recorded virtual trajectory. Additionally, clinical accuracy was evaluated using the Gertzbein-Robbins score by viewing the post-op scans.

• Human factors data were provided. Test participants representing the intended users of the device were included in the human factor validation testing. Observational data as well as interview data were recorded. The observation of participant performance and the assessment of their understanding of essential information through the interview confirmed that the design of the device, including the additional features of the latest version, is safe and effective for the intended users, uses and use environments.

•Software verification and validation testing was conducted as required by IEC 62304 and FDA guidance on general principles of software validation, January 11, 2002.

All performance testing demonstrates that the Caduceus S performs according to specifications and functions as intended.

The Caduceus S is substantially equivalent to its predicate, the cleared Caduceus S. Both systems have the same intended use, technological characteristics, and principles of operation. The expanded indications do not alter the intended surgical use of the device and do not affect its safety and effectiveness when used as labeled. None of the minor differences in technology raise new types of safety or effectiveness questions. Performance data demonstrated that the Caduceus S functions as intended.