April 1, 2026

Stereotaxis, Inc.
Angela McKnight
Senior Regulatory Affairs Specialist
710 Tucker Blvd.
Suite 110
Saint Louis, Missouri 63101

Re: K253473
Trade/Device Name: Synchrony
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: October 10, 2025
Received: October 10, 2025

Dear Angela McKnight:

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 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 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,

for: MARCO CANNELLA -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular 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)*
253473

Device Name
Synchrony

Indications for Use *(Describe)*
The Stereotaxis Synchrony™ system is an optional display and user interface package designed to consolidate the point of control of a medical lab.

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.

K253473 510(k) Summary [21 CFR 807.92]

Submitter

Name and Address: Stereotaxis, Inc.
710 N. Tucker Blvd.
Suite 110
St. Louis, MO 63101

Establishment Registration Number: 3003084417

Primary Contact: Angela McKnight
Senior Regulatory Affairs Specialist
(314) 303-6424
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Date Prepared: October 10, 2025

Device Information

Device Name: Synchrony

Classification/ Common Name: Programmable diagnostic computer

Classification: II

Product Code: DQK

Regulation Number & Name: 21 CFR 870.1425

Classification Panel: Cardiovascular

Predicate Information

	510(k) Number	Trade Name	Product Class	Product Code
Primary Predicate	K093092	Odyssey	II	DQK
Secondary Predicate	K072371	Odyssey	II	DXX

Device Description

The primary objective of Synchrony is to allow the clinician to customize layouts to address their needs which permit them to:

1. Consolidate the output multiple catheter laboratory displays on a single screen
2. Consolidate the control of multiple lab input devices with a single keyboard and mouse
3. Simplify the user interface
4. Streamline clinical workflows

Intended Use / Indications for Use

The Indications for Use / Intended Use are provided below:

- The Stereotaxis Synchrony system is an optional display and user interface package designed to consolidate the point of control of a medical lab.

Substantial Equivalence

Synchrony has the same intended use as and is substantially equivalent in design and functionality to Odyssey (K072371, cleared November 14, 2007) and Odyssey (K093092, cleared January 21, 2010). Synchrony and Odyssey are designed with a display monitor and user interface package that allows the clinician to view multiple diagnostic tool screens. The main differences of Synchrony relative to Odyssey are the image processing, video transfer and system communication.

Design verification and validation testing of Synchrony was conducted to show substantial equivalence to the predicate device. Testing conducted was identified on the basis of risk analysis activities performed to evaluate the impact of the modification on the device. Testing activities included electrical safety, functional performance and cybersecurity penetration tests.

Risk analysis activities were completed based on ISO 14971. Electrical/mechanical device safety and electromagnetic compatibility testing were conducted in accordance with IEC 60601-1 and 60601-1-2.

The modifications do not introduce or raise different questions about the safety or effectiveness of the device.

Performance Data

The determination of substantial equivalence for this device was based on a detailed device description and bench testing.

Test results demonstrate that Synchrony meets specifications and performs as intended. No new safety or performance issues were raised during testing. Synchrony is substantially equivalent to the predicate devices.

Conclusion

Based upon the documentation presented in this 510(k) it has been demonstrated that Synchrony is safe and effective for its intended use and Synchrony is substantially equivalent to the predicate devices Odyssey (K072371) and Odyssey (K093092).