April 23, 2026

Cortex, Inc.
Sarah Ware
Principal Regulatory Affairs Specialist
2755 Great America Way
Suite 401
Santa Clara, California 95054

Re: K261012
Trade/Device Name: OptiMap Catheter - 60mm (OPTI-CATH2-60)
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: MTD
Dated: March 26, 2026
Received: March 27, 2026

Dear Sarah Ware:

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,

MARCO CANNELLA -S

for:

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

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.	K261012

Please provide the device trade name(s).

OptiMap Catheter - 60mm (OPTI-CATH2-60)

Please provide your Indications for Use below.

The OptiMap™ Catheter is indicated for use in cardiac electrophysiology procedures to assist in the diagnosis of arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e. linear mapping catheters). The OptiMap™ Catheter may also be used for delivery of externally generated pacing stimuli.

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)

510(k) Summary for OptiMap Catheter

1. Submitter

Cortex, Inc.
2755 Great America Way
Suite 401
Santa Clara, CA 95054 USA

Contact:
Sarah Ware
Principal Regulatory Affairs Specialist
Phone: 651.287.5198
E-mail: sarah.ware1@bsci.com

Date Prepared: 25 March 2026

2. Device

Name of Device(s): OptiMap™ Catheter

Common Name: electrode mapping catheter
Classification Name: Electrode Recording Catheter or Electrode Recording Probe
Product Code: MTD
Device Class and Panel: Class II, Cardiovascular
Classification Regulation: 21 CFR 870.1220

3. Predicate Device

Subject Device	Predicate Device	Predicate 510(k)
OptiMap™ Catheter (OPTI-CATH2-60)	OptiMap™ Catheter (OPTI-CATH2-50)	K253205

4. Device Description

The OptiMap™ Catheter is a sterile, single-use device used to detect electrical potentials from the endocardial surfaces of the heart. It may also be used to deliver externally generated pacing stimuli. These signals may be used for analysis with a 3-D mapping system.

The catheter's distal end is an expandable basket with eight (8) longitudinal splines each having eight (8) electrodes spaced equally spaced along the length of the spline. When expanded, it forms a spherical or basket shape. An integrated Introducer Tool collapses the basket for insertion into a minimum 8.5 F sheath. The OptiMap™ Catheter family is available in two basket sizes; this submission is for OPTI-CATH2-60 only.

- Predicate: OPTI-CATH2-50 (50 mm basket size; K253205)
- Subject: OPTI-CATH2-60 (60 mm basket size)

5. Intended Use

Intracardiac electrophysiology mapping and pacing.

6. Indications for Use

The OptiMap™ Catheter is indicated for use in cardiac electrophysiology procedures to assist in the diagnosis of arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e. linear mapping catheters). The OptiMap™ Catheter may also be used for delivery of externally generated pacing stimuli.

7. Comparison of Technological Characteristics with the Predicate Device

There are no significant differences in the fundamental scientific technology between the predicate and subject devices. The OptiMap Catheter features the following similarities with the predicate device:

- Same intended use and indications for use
- Same principles of operation
- Same fundamental scientific technology
    - 3D basket shape mapping catheter with 8 radially spaced splines attached to a shaft and handle
    - Electrodes for intracardiac electrophysiology mapping and pacing
- Same materials
- Same catheter working length
- Same electrical ratings
- Same insertion method
- Same pacing parameters

The differences in technological characteristics involve the following:

- Basket size

8. Performance Data

Performance testing applicable to the subject device was completed to ensure it performs as intended per the product specifications and requirements, use with a compatible OptiMap mapping system. The following testing has been completed in support of the OptiMap Catheter, and all acceptance criteria were met in accordance with the protocols:

- Design Verification Testing
- Design Validation
- Formative Usability Evaluation
- Pre-clinical Animal Testing
- Biocompatibility Testing
- Sterilization Validation and Adoption
- Packaging Validation
- Electrical Safety Testing

The testing raised no new questions of safety or effectiveness, and the subject device is considered substantially equivalent to the predicate device based on the performance data collected.

9. Conclusion

The subject and predicate devices share the same intended use and have similar underlying technological characteristics (i.e., basket-shape mapping catheter intended for intracardiac electrophysiology mapping and pacing). Differences between the subject and predicate devices do not result in differences in overall device performance or fundamental scientific technology, and the subject device is considered substantially equivalent to the predicate device.