April 26, 2024

Osypka AG
Nicola Osypka
CEO
Earl-H.-Wood Str. 1
Rheinfelden, Baden 79618
Germany

Re: K232261
Trade/Device Name: TME Temporary Myocardial Electrode
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular Permanent Or Temporary Pacemaker Electrode
Regulatory Class: Class II
Product Code: LDF
Dated: March 26, 2024
Received: March 27, 2024

Dear Nicola Osypka:

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.

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,

Sara M. Royce -S
Digitally signed by Sara M. Royce -S
Date: 2024.04.26 14:32:30 -04'00'

Sara Royce
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)*

K232261

Device Name
TME Temporary Myocardial Electrodes

Indications for Use *(Describe)*

OSYPKA TME Temporary Myocardial Electrodes are intended for temporary cardiac pacing and sensing of the cardiac chambers after cardiac surgery to prevent postoperative bradycardia and conduction disorders.

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."

510(k) Summary

General Information:

Submitter: OSYPKA AG
Earl-H.-Wood-Str. 1
D-79618 Rheinfelden-Herten
Germany

Establishment Number: 3003923762

Contact: Dr. Nicola Osypka
Chief Executive Officer
email: n.osypka@osypka.de

Date Prepared:

Trade Name: TME Temporary Myocardial Electrodes
Common Name: temporary pacemaker electrode
Product Code: LDF
Regulation Number: 21 CFR §870.3680
Regulation Name: temporary pacemaker electrode
Cardiovascular
Class: II

Predicate Devices:

510(k) Number	Description
K850622	Oscor Inc. Model TME 64S Bipolar Temporary Heart Wire

Device Description:

OSYPKA TME® temporary myocardial electrode is a device consisting of flexible insulated electrical conductors with one end connected to an external pacemaker pulse generator and the other end applied to the heart. The device is used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.
The conductors or wires are typically 60cm or 220cm long and can be fixated to the heart either with the help of a suture (V-hook), or directly with the attached heart needle (zigzag, and tines fixation types). The heart needle is cut off after fixation (Zigzag, Tines anchor) and disposed of. The thoracic needle is used to lead the wires to the outside of the patient's body to allow connection to the external pulse generator. The thoracic needle(s) is then also disposed of.

OSYPKA TMEs are supplied as unipolar, bipolar, and quadripolar version. There are two options for connection to an external cardiac pacemaker or cable: with 2 mm adapter or Confix. The preassembled Confix connectors can be connected directly to an extension lead or to the cardiac pacemaker after the thorax needle has been cut off.
The device is supplied sterile, non-pyrogenic and intended for single use only.

Indications for Use:

OSYPKA TME Temporary Myocardial Electrodes are intended for temporary cardiac pacing and sensing of the cardiac chambers after cardiac surgery to prevent postoperative bradycardia and conduction disorders.

Comparison to Predicate and reference Devices:

The OSYPKA TME Temporary Myocardial Electrodes are substantially equivalent to the predicate and reference devices in terms of design, materials, and performance. The predicate and subject device have similar indications and identical construction.

Differences in Indications for Use:

The Indications for Use are very similar to the predicate device. They are intended for the same use and compatible with the same pacing devices.

Packaging:

Each TME Temporary Myocardial Electrode is packaged in: double pouch consisting of Tyvek®/Poly pouches. The double pouched sterile TME devices are packed in a cardboard box in quantities of 1,5 or 25 per box.

Non-Clinical Performance testing:

The TME Temporary Myocardial Electrodes been thoroughly tested through verification of product specifications, user requirements, and device compatibility to ensure equivalency to the predicate device. The following quality assurance and performance testing includes:

- Bending Strength
- Dielectric Strength
- Cannulas
- Surfaces, Edges, and Corners
- Lead Resistance
- Tensile Strength
- Corrosion Resistance
- Retention Force
- Withdrawal Force
- Patient Connection Line

Sterilization

The TME Temporary Myocardial Electrodes are sterilized using the same Ethylene Oxide (ETO) Sterilization process and equipment as the predicate electrodes.

Biocompatibility

Biocompatibility testing was completed on finished packaged devices that had gone through controlled manufacturing processes and ETO sterilization prior to physical and chemical analysis, and biocompatibility testing. TME Temporary Myocardial Electrodes were found to be biocompatible with the following ISO 10993-1 tests based on the use type and duration of contact:

- Chemical analysis and characterization
- Cytotoxicity
- Sensitization
- irritation
- Toxicity
- Implantation
- Genotoxicity

Comparison to Predicate and reference devices:

The TME Temporary Myocardial Electrodes is substantially equivalent to the predicate based on the following technological elements:

Technology and construction: The construction of the subject device and predicate device are identical. Osypka AG manufactures the complete line of Unipolar, Bipolar & Quadripolar Temporary Myocardial Heartwires for Oscor. There are no material, construction, specification, manufacturing process, or sterilization process differences.

Environment of Use: The use environments are the same. The TME are provided sterile. The TME are temporarily implanted into the myocardium of the heart and connected to an external pacemaker. The subject and predicate devices must be used by a physician in a healthcare facility.

Patient Population: The patient populations are the same as the predicate and reference devices, namely, pediatrics, children, and adult patients.

The following technological differences exist between the subject and predicate devices:

There are no technological differences between the subject and predicate devices. The construction of the subject device and the predicates are the same.