August 7, 2020

Cardinal Health
Christine Kuntz Nassif
Manager, Regulatory Affairs
777 West Street
Mansfield, MA 02048

Re: P190007
Trade/Device Name: Kendall™ Multi-Function Defibrillation Electrodes, Medi-Trace™ Cadence Multi-Function Defibrillation Electrodes, Physio-Control/Stryker QUIK-COMBO Pacing/Defibrillation/ECG Electrodes
Product Code: MKJ
Filed: March 25, 2019
Amended: October 30, 2019, December 19, 2019, December 20, 2020, February 28, 2020, and July 29, 2020

Dear Christine Kuntz Nassif:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Kendall™ Multi-Function Defibrillation Electrodes, Medi-Trace™ Cadence Multi-Function Defibrillation Electrodes, Physio-Control/Stryker QUIK-COMBO Pacing/Defibrillation/ECG Electrodes (the "Multi-Function Defibrillation Electrodes"). These devices are indications for these devices is as follows:

> The Multi-Function Defibrillation Electrodes are intended to transfer energy from a cardiac defibrillator or pacer to the body of a patient for the purpose of defibrillation, synchronized cardioversion, pacing, or for ECG monitoring.
>
> The Kendall™ and Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrodes with connectors intended for use with Physio-Control LIFEPAK (LP) defibrillators are compatible with Physio-Control / Stryker LP 15, LP 20, LP 20E, LP 1000, LP CR Plus, and LP Express defibrillators with the exception of the Kendall™ 1010P Adult Multi-Function Defibrillation Electrode, which is compatible with Physio-Control LP 20 and LP 20e defibrillators and the Physio-Control FAST-PATCH® cable.
>
> The Medi-Trace™ Cadence Pediatric Multi-Function Defibrillation Electrodes with connectors intended for use with Physio-Control / Stryker defibrillators are compatible with Physio-Control LP 15, LP 20, and LP 20e defibrillators.

The Kendall™ and Medi-Trace™ Cadence Adult Multi-Function Defibrillation Electrodes with connectors intended for use with ZOLL defibrillators are compatible with ZOLL R Series BLS, R Series Plus, R Series ALS, X Series, and Propaq MD defibrillators.

The Physio-Control/Stryker QUIK-COMBO Adult pacing/defibrillation/ECG electrodes and QUIK-COMBO Pediatric pacing/defibrillation/ECG electrodes are compatible with LP 15, LP 20, and LP 20e defibrillators. The Physio-Control/Stryker QUIK-COMBO pacing/defibrillation/ECG electrode with REDI-PAK Preconnect system is compatible with LP 15, LP 20, LP 20e, LP 1000, LP CR Plus, and LP EXPRESS defibrillators.

We are pleased to inform you that the PMA is approved. You may continue commercial distribution of the device upon receipt of this letter. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved for the models as shown below:

Model	**Item No.**	**Shelf Life (Months)**
Kendall 20550 Adult Multi-Function Defibrillation Electrodes, Radiotransparent, Medtronic	20550	24
Kendall 20770 Adult Multi-Function Defibrillation Electrodes, Radiotransparent	20770	24
Medi-Trace Cadence Adult, Multi-Function Defibrillation Electrode, Quik-Combo	22550A	24
Medi-Trace Cadence Adult Preconnect Defibrillation Electrode	22550PC	24
Medi-Trace Cadence Adult Multi-Function Quik-Combo Radiotransparent Defibrillation Electrode	22550R	24
Medi-Trace Cadence Adult Multi-Function Defibrillation Electrodes, Preconnect	22770PC	24

Medi-Trace Cadence Adult Radiotransparent Connector Multi-Function Defibrillation Electrodes	22770R	24
Quik-Combo Radiotransparent Defibrillation Electrode	PM20003	30
Quik-Combo Defibrillation Electrode	PM20005	30
Quik-Combo Redi-Pak Preconnect Defibrillation Electrode	PM20022	30
Medi-Trace Cadence Pediatric Multi-Function Defibrillation Electrodes, Quik-Combo Connector	22550P	24
Medi-Trace Cadence Pediatric Radiotransparent Connector, Defibrillation Electrode	22770P	24
Quik-Combo Radiotransparent Pediatric Defibrillation Electrode	PM20012	18
Kendall 1010P Defibrillation Electrode	31177705	24
Kendall 1310P Defibrillation Electrode	31319281	24
Kendall 1410Z Defibrillation Electrode	31469219	24

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI

website, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" https://www.fda.gov/media/81431/download.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems and on combination product postmarketing safety reporting is available at (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the postmarketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on

the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Luke Ralston at 301-796-6362 or Luke.Ralston@fda.hhs.gov.

Sincerely,

Jessica E. Paulsen -S

Jessica Paulsen
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