January 11, 2021

Philips North America LLC
Neha Hardiya
Regulatory Affairs Specialist
22100 Bothell Everett Hwy
Bothell, Washington 98021

Re: K203231
Trade/Device Name: Switched Internal Paddles
Regulation Number: 21 CFR 870.5300
Regulation Name: DC-Defibrillator (Including Paddles)
Regulatory Class: Class II
Product Code: LDD
Dated: December 17, 2020
Received: December 18, 2020

Dear Neha Hardiya:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Jennifer Shih Kozen
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)*
K203231

Device Name
Switched Internal Paddles

Indications for Use *(Describe)*
The Switched Internal Paddles are indicated for use in the treatment of ventricular fibrillation by manual defibrillation being provided directly to the heart during open-chest surgical procedures.

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.

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5. 510(k) Summary

510(k) Summary

This 510(k) summary was prepared in accordance with the requirements of 21 CFR 807.92.

I. Contact Information

Submitter	
Name	Philips North America LLC (dba Philips Medical Systems)
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Phone No.	425-908-2569
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Date Prepared	January 07, 2021

II. Device Information

Trade Name	Switched Internal Paddles
Common Name	Dc-Defibrillator, Low-Energy, (Including Paddles)
Classification	Class II 21 CFR 870.5300, DC-defibrillator (including paddles)
Product Code	LDD

III. Predicate Device Information

Primary Predicate Name	HeartStream XL Defibrillator/Monitor
510(k) Submission No.	K021453
Classification	Class II (for LDD product code) 21 CFR 870.5300, DC-defibrillator (including paddles)
Product Code	LDD (Class II features); MKJ (Class III features[1])
Secondary Predicate Name	Sterilizable Internal Defibrillation Paddles for use with LIFEPAK defibrillators/monitors
510(k) Submission No.	K182503
Classification	Class II 21 CFR 870.5300, DC-defibrillator (including paddles)
Product Code	LDD

[1] There are no Class III features in this submission; the primary predicate referenced is only for the Switched Internal Paddles (LDD) that were included in the overall submission; this is the reason for multiple product codes in K021453.

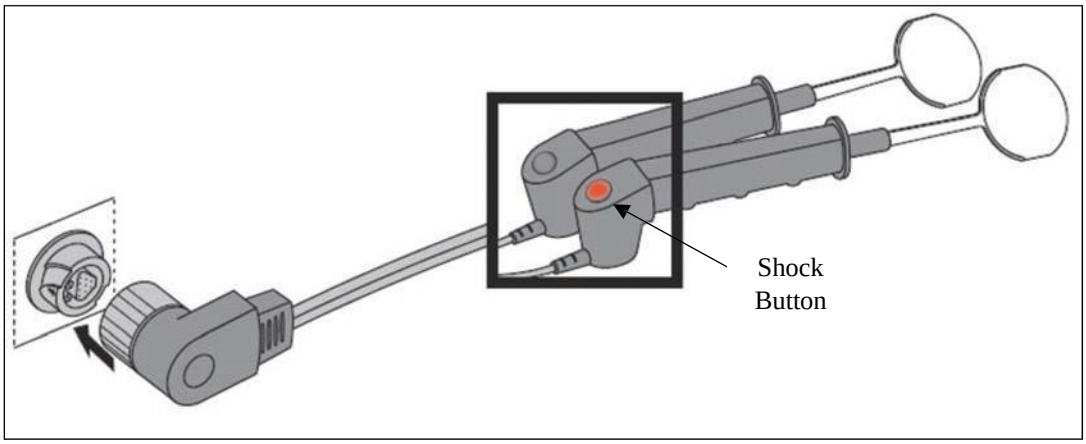
Prior Submissions

This is an original submission. There has been no prior submission for the subject device.

IV. Device Description

The Switched Internal Paddles are used for defibrillation during open-chest (intrathoracic) procedures. These paddles have a shock button located on the right-hand paddle shown in **Figure 5-1**. This shock button allows the user to deliver a defibrillation shock holding the paddles to discharge the defibrillator remotely.

Figure 5-1. Shock Button on Switched Internal Paddles



The reusable switched internal paddles are shipped non-sterile and are sterilized by the health care provider prior to each patient use. These switched internal paddles are accessories to compatible Philips HeartStart Defibrillators as detailed in **Table 5-1**, and are identified by the M47xxA series model numbers (where "xx" is a variable integer), as listed below in **Table 5-1.** These paddles can be used on adult and pediatric populations per the indications for use of the compatible defibrillators.

Table 5-1. Switched Internal Paddles Model Numbers

Model No.	Product Name	Compatible Devices
M4741A	Extra Large Switched Internal Paddles, 7.5 cm	HeartStart MRx and HeartStart XL+
M4742A	Large Switched Internal Paddles, 6.0 cm	
M4743A	Medium Switched Internal Paddles, 4.5 cm	
M4744A	Small Switched Internal Paddles, 2.8 cm	

The switched internal paddles are compatible with the HeartStart MRx and HeartStart XL+. The switched internal paddles are used with the HeartStart Defibrillators in Manual Mode only and cannot be used with the defibrillators in the AED Mode. The compatible defibrillators have a built-in maximum limit of 50 Joules when used with switched internal paddles.

Reason for Change

This submission is to notify the FDA of our intent to market the Switched Internal Paddles with the modified Instructions for Use (IFU) that includes narrowed reprocessing instructions for switched internal paddles. The modified IFU includes the maximum number of allowable reprocessing cycles. A comprehensive list of updates made to the Switched Internal Paddles, including updates that did not specifically require submission of a premarket notification, is provided below in **Table 5-2**.

Table 5-2. List of Changes Made to Switched Internal Paddles

Change	Description
Reprocessing Instructions	Instructions for reprocessing Switched Internal Paddles have been narrowed to include maximum number of reprocessing cycles (100) and have narrowed the preferred cleaning agent (quaternary ammonium based detergent) and sterilization method (steam sterilization) per user preference. These changes to the instructions have been re-verified and re-validated; results are summarized in **Section 13**.
Material Change	The resin is a non-patient contacting material used as an assembly aid. Resin material used in the switched internal paddles' handle at the switch termination has been replaced to support the end of life resin material.
Engineering Specification Update	Engineering specification for the switched internal paddles has been made more detailed to include more comprehensive requirements including clarification and modification in accordance with the state-of-the-art standards, since switched internal paddles were last cleared in 2002.
Assembly Drawing Update	Assembly drawing has been made more detailed to include the related information from the engineering specification, assembly aid material change, and minor modifications for clarity.
Fastener Change	fastener used to secure the high voltage lead wires to the base of the electrode has been changed to resolve potential over-molding process issues.
Device labeling updates	Labeling for switched internal paddles has been updated to include in the correct legal manufacturer's address, addition of UDI (Unique Device Identifier) Tag and UDI

Change	Description
	attachment wire for assisting users in tracking the reprocessing cycles.
Biocompatibility Testing	Biocompatibility testing was repeated for confirmatory purposes to ensure any unanticipated material drift since the last product iteration, as described in **Table 10-4** and **Table 13-2**, to ensure that the switched internal paddles remain in compliance with the requirements of ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.

While previous premarket submissions included Switched Internal Paddles, Switchless Internal Paddles, and External Paddles, this Special 510(k) submission only includes Switched Internal Paddles and therefore, the updated IFU only includes instructions for using and reprocessing Switched Internal Paddles.

V. Intended Use

Note that the intended use statement has been narrowed to include the specific compatible HeartStart Defibrillators, but the intended use for switched internal paddle remains functionally unchanged.

The Switched Internal Paddles are intended for use with HeartStart defibrillators to defibrillate the heart during open-chest surgical procedures.

Indications for Use:

The Switched Internal Paddles are indicated for use in the treatment of ventricular fibrillation by manual defibrillation being provided directly to the heart during open-chest surgical procedures.

VI. Comparison of Technological Characteristics with the Predicate Device

The intended use and technology used with the Switched Internal Paddles remains unchanged by the labeling modifications for reprocessing internal paddles. **Table 5-3** below provides a summary of comparison between the Switched Internal Paddles that is the subject of this 510(k) and the primary predicate device Switched Internal Paddles included with HeartStart XL Defibrillator/Monitor cleared per K021453.

Table 5-3. Comparison of Technological Features with the Primary Predicate Device

Similarities	
Intended User	No change.
Environmental Specification	No change.
Physical Dimensions	No change.
User Interface	No change to the physical device user interface.
Differences	
Intended use	The intended use statement has been narrowed to include the specific compatible HeartStart Defibrillators, but the intended use for switched internal paddle remains functionally unchanged.
Scope of Devices	Narrowed to only include Switched Internal Paddles (Switchless and External paddles removed).
Internal Paddle Checks	Continuity Check In comparison with the primary predicate device, Converted the frequency of checks from 3 months (current labeling) to every 25 reprocessing cycles, to ensure checks are usage based and not only time based.
Reprocessing Instructions	Narrowed to allow a maximum of 100 reprocessing cycles.
Material	Resin material used in the switched internal paddles' handle at the switch termination has been replaced with a similar resin to support the end of life resin material. The resin is a non-patient contacting material used as an assembly aid.
Cleaning Instructions	Narrowed to only quaternary ammonium detergent as the cleaning agent. To reduce ambiguity, recommendations on rinsing time, air drying, and performing a post-cleaning visual inspection as part of the cleaning process were added.
Sterilization Instructions	To reduce ambiguity, recommendations on dry time and updated exposure time for gravity steam were added. All sterilization options other than steam sterilization were removed.
Transport and Storage	To reduce ambiguity, recommendations added to the IFU.
Warning and Cautions	Cautions for paddle health checks and handling switched internal paddles during use added and also limited rewording for clarity.

VII. Performance Data

The following performance data were provided in support of substantial equivalence determination.

Bench Testing

Bench testing was performed to re-verify system level device specifications including hardware testing, biocompatibility, cleaning and sterilization validation, and labeling verification testing. The test result confirmed that the Switched Internal Paddles meets the specifications and complies with the requirements of IEC 60601-1:2005/(R)2012+A1:2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, IEC 60601-2-4:2010/AMD1:2018, Medical Electrical Equipment: Particular Requirements for Basic Safety and essential performance of cardiac defibrillators, and ISO 17665-1:2013, Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

Biocompatibility

Switched Internal Paddles were re-tested for biocompatibility, as these paddles are used for defibrillation during open-chest procedures. In accordance with *Guidance for Industry and FDA Staff - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (2020)*, the classification of the switched internal paddles is 'Contact Duration' – A limited (<24h) External communicating device and the nature of body contact is tissue/bone/dentin.

Extra Large Switched Internal Paddles with the largest surface area (Model No. M4741A) were used to maximize patient contact region in biocompatibility tests to simulate a worst-case scenario. Test results confirmed that the Switched Internal Paddles met acceptance criteria for cytotoxicity, sensitization, irritation or intra-cutaneous reactivity, acute systemic toxicity, and material mediated pyrogenicity and are in compliance with the requirements of ISO 10993-1, Biological evaluation of medical devices. **Table 5-4** below provides the evaluated biocompatibility endpoints and the test performed for Switched Internal Paddles.

Table 5-4: Switched Internal Paddles Biocompatibility Testing

Evaluation Endpoint	Test Performed	Applicable Standard
Cytotoxicity	Cytotoxicity- MEM Elution Method	ISO 10993-5:2009
Sensitization	ISO Guinea Pig Maximization Sensitization Test	ISO 10993-10:2010
Irritation or intra-cutaneous reactivity	ISO Skin Irritation Study in Rabbits	ISO 10993-10:2010
Acute System Toxicity	ISO Systemic Toxicity Study in Mice	ISO 10993-11:2017
Material Mediated Pyrogenicity	Pyrogenicity Study in Rabbits	ISO 10993-11:2017

Software Verification and Validation

The modified Switched Internal Paddles do not use software for its function nor required any software modifications for compatibility with the HeartStart Defibrillators; therefore, software testing is not applicable for this submission.

Electrical Safety

Electrical safety testing was conducted for the proposed modifications made to Switched Internal Paddles. Non-clinical testing was performed to demonstrate that the device is substantially equivalent to its predicate. Test results confirmed that the subject device complies with the ES60601-1:2005/(R)2012+A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance and IEC 60601-2-4:2010, Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators. Modifications made to the Switched Internal Paddles did not impact the electromagnetic compatibility of the device.

Performance Testing-Usability

Switched Internal Paddles were tested for usability per the narrowed instructions for cleaning and sterilization to ensure the subject device is as safe and effective as the predicate. Note that the method of operation and performance of the device has not been impacted due to the proposed modification. This test was conducted with fifteen (15) participants (eleven (11) sterile processing technicians and four (4) surgical technicians in an operating room and a central processing/sterilization room in a hospital (intended use environment). The test results confirmed that the subject device is substantially equivalent when used per the modified instructions for use and complies with the requirements of ANSI AAMI HE75:2009/(R) 2018, Human Factors Engineering - Design of Medical Devices and *Guidance for Industry and Food Drug Administration Staff-Applying Human Factors and Usability Engineering to Medical Devices (2016)*.

VIII. Conclusions

The results of the substantial equivalence assessment, taken together with the as-expected and confirmatory results of bench testing, electrical testing, biocompatibility testing, and usability testing demonstrate that the Switched Internal Paddles with the modifications described in this premarket notification does not raise different questions of substantial equivalence when compared to the predicate. The device performs as intended and has performance characteristics that are substantially equivalent to the Switched Internal Paddles cleared per K021453.