August 13, 2021

Abbott (St. Jude Medical)
Juni Sarkar
Sr. Regulatory Affairs Specialist
15900 Valley View Ct.
Sylmar, California 91342

Re: K212206
Trade/Device Name: Jot Dx Insertable Cardiac Monitor
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MXC, DSI
Dated: July 14, 2021
Received: July 15, 2021

Dear Juni Sarkar:

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 W. Shih -S

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)*
K212206

Device Name
Jot Dx™ ICM DM4500

Indications for Use *(Describe)*
The Jot Dx™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias. It is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation.

The Jot Dx™ ICM has not been specifically tested for pediatric use.

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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510(k) SUMMARY

Date Prepared:	July 14, 2021	
Submitter:	Abbott (formerly St. Jude Medical) Cardiac Rhythm Management Division	
Address:	15900 Valley View Ct. Sylmar, CA 91342 USA	
Phone:	(818) 362-6822	
Establishment Registration:	2017865	
Contact Person:	Juni Sarkar Senior Regulatory Affairs Specialist (818) 294-3429 juni.sarkar@abbott.com	Jennifer Dunham Sr. Manager, Regulatory Affairs (818) 383-1630 jennifer.dunham@abbott.com
Trade Name/Proprietary Name:	Jot Dx™ Insertable Cardiac Monitor	
Common Name:	Insertable Cardiac Monitor	
Model Number:	DM4500	
Classification Name:	21 CFR 870.2800, Medical magnetic tape recorder	
Product Code:	MXC, DSI	
Classification:	Class II	
Pediatric Use:	The Jot Dx™ Insertable Cardiac Monitor has not been specifically tested in pediatric patients.	

LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED

510(k) K202888: Confirm Rx™ Insertable Cardiac Monitor System

INDICATIONS FOR USE

The are no changes to the Indications for Use as a result of this submission. The Indications for Use for the Jot Dx™ Insertable Cardiac Monitor (ICM) system are as follows:

> The Jot Dx™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias. It is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation.
>
> The Jot Dx ICM has not been specifically tested for pediatric use.

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PRODUCT DESCRIPTION

The candidate Jot Dx™ ICM DM4500 System, predicated on the Confirm Rx™ ICM DM3500 System, consists of the following key features and components:

- **Jot Dx™ ICM Model DM4500 Implantable Device (Figure 2)**: The ICM is intended as a minimally invasive, implantable diagnostic monitoring device, with subcutaneous electrodes, looping memory, and automatic as well as patient-activated EGM storage capability, which help physicians monitor, diagnose, and document patients who are susceptible to cardiac arrhythmias. Specific features include:
  - Patient-initiated triggering of EGM storage using the myMerlin™ mobile application. This includes capability for the patient to identify symptoms, which are stored with the EGM for physician review.
  - Automated triggering of EGM storage when tachycardia, bradycardia, or pauses are detected; with physician-programmable values for pause duration, bradycardia rate, tachycardia rate, and number of tachycardia intervals.
  - Automated triggering of EGM storage when atrial fibrillation (AF) is detected, with physician programmable values for AF duration.
  - The ability to identify EGM anomalies as a consequence of noise or vigorous activity and inhibit EGM storage as applicable.
  - Remote monitoring capabilities.
- **Implant Tools:** Incision tool (**Model DM3520; Figure 2, a**) and Insertion tool (**Model DM3510; Figure 2, b**) are used to implant the device subcutaneously. The implantable device is pre-loaded into the insertion tool and packaged together with the incision tool.
  - The DM3520 incision tool is used to make an angled cut to the skin during the insertion procedure.
  - The blunt dissection tip of the DM3510 insertion tool is inserted just past the skin creating a subcutaneous pocket parallel to the skin (**Figure 3**). With the insertion tool in place as far as it can go, until the flared edge contacts the incision site, the plunger is withdrawn to drop the pre-loaded device into the insertion channel. The plunger is advanced to insert the device into the subcutaneous pocket (**Figure 3**). This completes insertion (implantation) of the ICM, and the incision is closed per standard of care.

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Figure 1: Jot Dx ICM DM4500

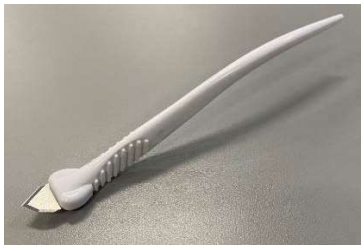
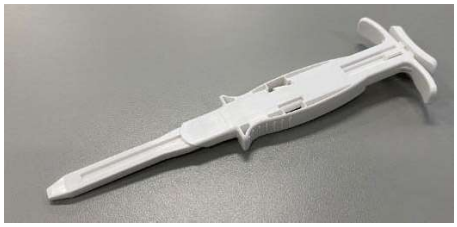
(a)  (b) 

Figure 2: Implant tool DM3520 and Incision tool DM3510

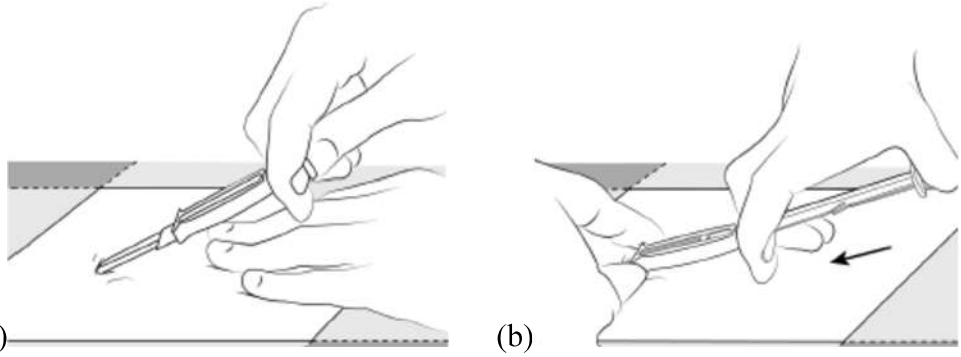


Figure 3: Insertion Process

- **Confirm Rx ICM Accessory Kit DM3500A:** The Confirm Rx™ ICM Accessory Kit Model DM3500A (originally cleared via 510(k) K202876) is a sterilized, standalone, one-time use convenience kit containing the Insertion Tool DM3510 and the Incision Tool DM3520. The contents of this package include implant tools which are used for both the candidate Jot Dx™ ICM DM4500 and the predicate Confirm Rx™ ICM DM3500 (K202888) and allow for availability of the implant tools separately in a convenience kit, without the pre-loaded ICM in the insertion tool.

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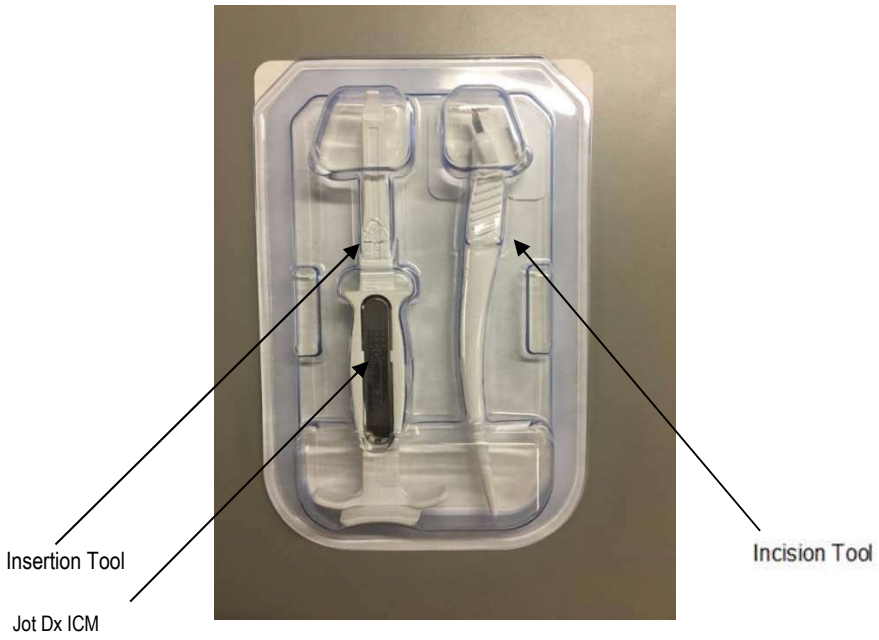

Figure 4: Jot Dx™ ICM DM4500 and Accessories in the Sterile Packaging

- **Magnet**: The magnet facilitates faster startup of Bluetooth connection and provides user authentication (required for programmer sessions).
- **Clinician Programmer (Merlin PCS Programmer Model 3650)**: The Merlin PCS 3650 Programmer operates using Model 3330 software. The clinician programmer provides the means for the physician to program device parameters and retrieve diagnostic information from the device, including electrograms, heart rate history, episode duration, and trend information. The clinician programmer, using a Bluetooth® dongle, a device-MDDS component, communicates with the Jot Dx™ ICM DM4500 device with Bluetooth® telemetry (also referred to as Bluetooth® Low Energy or Bluetooth® LE). Programmer software Model 3330 v25.3.1 or higher contains support for the Jot Dx™ ICM device and include tabs within the user interface for Implant View and Reason for Monitoring features.
  - **Implant View** is designed to streamline programming at the time of implant. Upon initial interrogation at implant, the programmer automatically displays the Implant View in which the user can immediately input device and patient information to be stored onto the device, as well as set the Reason for Monitoring.
  - **Reason for Monitoring** allows the user to select from a list of possible conditions for which the patient is receiving the device (such as Syncope, Ventricular Tachycardia, Palpations, etc). The programmer then sets the AF duration parameter and EGM storage priority based on the reason selected. These parameters can be manually adjusted by the user later, if customization is preferred.
- **myMerlin™ Mobile Application** (Model APP1000 (Android) and APP1001 (iOS)): The mobile application provides the means for the patient to activate EGM recording in the Jot

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Dx™ ICM DM4500 device, with data pass-through functionality to enable physician follow-up via the Merlin.net Patient Care Network. Software v1.0.6000 or higher contain support for the Jot Dx™ ICM device. Patients who do not supply their own mobile device may be provided with an Abbott-issued off the shelf Android mobile device, which is not part of the medical device.

- **Remote Care/Clinician Portal** (Merlin.net MN5000 Report Generator): The Merlin.net system allows physicians to remotely monitor and diagnose patients' cardiac events. The Merlin.net MN5000 v7.8 or higher software contains support for the Jot Dx™ ICM DM4500 device.

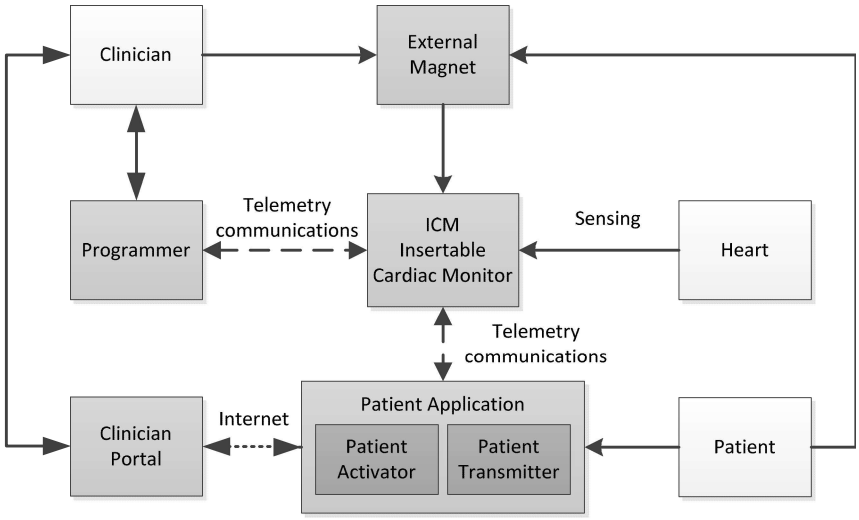

Figure 5: Block Diagram of Jot Dx™ ICM System

TECHNOLOGICAL CHARACTERISTICS

The candidate Jot Dx™ ICM DM4500 and the predicate Confirm Rx™ ICM DM3500 (K202888) are 49 x 94 x 3.1 mm in dimension and use Bluetooth® wireless telemetry to communicate with external devices, including the clinician programmers and the myMerlin™ mobile application. An external magnet facilitates faster startup of Bluetooth® connection and provides user authentication (required for programmer sessions). The remote monitoring equipment for the candidate Jot Dx™ ICM DM4500 and the predicate Confirm Rx™ ICM DM3500 (K202888) is the myMerlin™ mobile application, installed on a patient's or Abbott-provided mobile device, using built-in cellular or Wi-Fi connectivity. The candidate Jot Dx™ ICM DM4500 will continue to use the same technology as the predicate Confirm Rx™ ICM DM3500 (K202888). The myMerlin™ mobile application provides the means for the patient to activate EGM recording in the Jot Dx™ ICM device, with data pass-through functionality to enable physician follow-up via the Merlin.net Patient Care Network (clinician portal). See **Figure 5** for a block diagram of the Jot Dx™ ICM system.

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510(k) SUMMARY

The subject of this premarket notification is the candidate Abbott-branded Jot Dx™™ ICM DM4500 System to be added to Abbott's ICM device portfolio, which is identical to the predicate Confirm Rx™ ICM DM3500 (K202888) system aside from name, model number, and corresponding laser marking. There are no changes to the predicate (K202888) Confirm Rx™ Insertable Cardiac Monitor DM3500, the insertion tool DM3510, the incision tool DM3520, or the myMerlin™ mobile applications within the scope of this premarket notification. The Merlin PCS 3650 programmer software model 3330 v25.3.1 or higher and Merlin.net MN5000 v7.8 or higher include support for Jot Dx™ ICM. The magnet is Class I exempt device-MDDS.

The fundamental technological characteristics of the candidate Jot Dx™ ICM DM4500 are not changing in comparison to the predicate device, the current Confirm Rx™ ICM DM3500 (510(k) K202888). The candidate Jot Dx™ ICM DM4500 system has the same:

- Intended Use and Indications for Use
- Operating rules
- Device/tool functionality
- Packaging materials and process
- Shelf life
- Device Longevity
- Software

NON-CLINICAL TEST SUMMARY

The candidate Jot Dx™ ICM DM4500 is identical to the predicate Confirm Rx™ ICM DM3500 (K202888), aside from name, model number, and corresponding laser marking. The risk analysis method used to assess the impact of the addition of the candidate Jot Dx™ ICM DM4500 documents the investigation of hazards and mitigation of associated risks and reports the result of the investigation. The risk analysis method used to assess the impact of the modifications was a Failure Mode and Effects Analysis (FMEA/FMECA). It was determined that the overall risk is acceptable. Completion of all verification and validation activities demonstrated that the candidate Jot Dx™ ICM DM4500 meets its predetermined design and performance specifications and that the product is substantially equivalent to the predicate device (Model DM3500, K202888).

SUBSTANTIAL EQUIVALENCE

The candidate Jot Dx™ ICM system is an Abbott-branded Insertable Cardiac Monitoring device which is identical to the predicate Confirm Rx™ ICM DM3500 (K202888) aside from name, model number, and corresponding laser marking (as shown Figure 1). The candidate Jot Dx™ ICM DM4500 is identical in design and function and has the same indications and intended use as the predicate Confirm Rx™ ICM DM3500 (K202888). Both the candidate Jot Dx™ ICM DM4500 and the predicate Confirm Rx ICM DM3500 (K202888) have the same function and fundamental scientific technology. The minor differences in name, model number, and laser marking do not raise new issues of safety and effectiveness. Thus, the candidate Jot Dx™ ICM

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DM4500 system is substantially equivalent to the predicate Confirm Rx™ ICM DM3500 system (K202888).

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary device and system verification testing conducted on the candidate Jot Dx ICM DM4500 System supports a determination of substantial equivalence to the predicate Confirm Rx™ ICM DM3500 System.

Completion of all verification activities demonstrated the candidate Jot Dx™ ICM DM4500 device meets its predetermined design and performance specifications and that the product is substantially equivalent to the predicate Confirm Rx™ ICM device (K202888). The results of the testing show that the candidate Jot Dx ICM DM4500 system performs as intended and is safe for its intended use.

CONCLUSION (SUBSTANTIAL EQUIVALENCE)

The results of the verification and validation tests and the risk analysis have demonstrated the candidate Jot Dx™ ICM DM4500 system functions in accordance with product specifications. The candidate Jot Dx™ ICM DM4500 system is substantially equivalent in terms of safety and technological characteristics to the identified predicate device (Confirm Rx™ ICM System; K202888). Product verification and validation testing demonstrate that the candidate Jot Dx ICM system is as safe and as effective and performs as well as the predicate system (K202888). The indications for use are not changed for the candidate Jot Dx™ ICM DM4500. The fundamental scientific technology of the candidate Jot Dx™ ICM DM4500 system remains the same as the predicate Confirm Rx™ ICM DM3500 system (K202888). Thus, the candidate Jot Dx™ ICM DM4500 System is deemed to be substantially equivalent to the predicate Confirm Rx™ ICM DM3500 cleared via 510(k) K202888.