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Life Expectancy Of Cardiovascular Devices: The Fda Conisderations& Requirements

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Abstract

Cardiac implantable electronic devices are designed to help control or monitor irregular heartbeats in people with certain heart rhythm disorders and heart failure. Medical devices must meet strict regulations for both efficiency as well as security. The FDA checks for developing safety concerns once a medical device is on the market as part of our ongoing commitment to promote patient safety, and will take appropriate action when we become aware of problems that could threaten patients. In order to optimize the expected lifespan of medical devices and to ensure that it is accessible and in great condition when patient care is provided, lifecycle management is crucial. Presently, a number of obstacles prevent wearable technologies from being widely used in healthcare settings. Devices will become increasingly capable and an essential tool in our tools for cardiovascular practise as sensor and computing technology advance. For the purpose of ensuring their efficacy and safety, these devices must be regulated through evaluation frameworks and sufficient regulatory oversight procedures.

Key words: Medical devices, Cardiac devices, Premarketing Approval (PMA), Life expectancy, MedSun, MedWatch

INTRODUCTION:

Today, there are an estimated 2 million different kinds of medical devices on the world market, categorized into more than 7000 generic devices groups.
A medical device can be any instrument, apparatus, implement, machine, appliance, implant, and reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose [1]
The Center for Devices and Radiological Health of the US Food and Drug Administration (FDA) is responsible for overseeing medical device regulation. The Center for Devices and Radiological Health is tasked with safeguarding and advancing public health by ensuring the efficacy, dependability, and quality of medical devices, the security of radiation-emitting products, encouraging innovation, and disseminating accurate, factual information about the products we regulate to the general public throughout the full life expectancy of the product.

Pacemakers are programmable artificial electrical pulse generators that can emit pulses up to 300 times per minute with a frequency of 0.5 to 25 milliseconds and an output of 0.1 to 15 volts. Whether the pacemaker is temporary or permanent, the cardiologist or pacemaker technician will be able to examine and control the pacing rate, pulse width, and voltage. Typically, pacemakers are either external or internal. The external variant is almost always used to ease a surgical procedure or to temporarily stabilize the patient. The permanent, implantable variety is typically far more sophisticated than the transient, external kind [2].

Several international classification systems are used for medical devices. The WHO is currently working to achieve harmonization in medical device nomenclature, which is thought to impact patient safety significantly. This is particularly important in identifying any adverse incident reports and recalls.

The Center for Devices and Radiological Health (CDRH) of the FDA is in charge of overseeing businesses that produce, repackage, relabel, and/or import medical devices sold in the United States. Additionally, the CDRH oversees the regulation of both medical and nonmedical radiation-emitting electronic gadgets, including lasers, x-ray machines, ultrasound devices, microwaves, and colored televisions.

Cardiovascular pacemakers are medical devices that send impulses to the conduction system to start the contraction process. Since 1958, when the first cardiac pacemaker was implanted (Atlee and Bernstein, 2001), cardiac pacing has developed into a recognized therapeutic method.

Class	Risk	Controls	Submission
I	Lowest	General	• Exempt • 510(k)
II	Moderate	General and Special	• Exempt • 510(k)
III	High	General and PMA	PMA

Table1: classification of medical devices

Overview

A pacemaker is a tiny device that is implanted in the chest to assist in heartbeat regulation. It serves as a safeguard against the heart beating too slowly. The placement of a pacemaker inside the chest necessitates surgery. Another term for a pacemaker is a cardiac pacing device.

Types

Depending on condition, might have one of the following types of pacemakers.

Single chamber pacemaker: To your heart's right ventricle, this kind typically delivers electrical impulses.

Dual chamber pacemaker: This kind sends electrical signals to the right ventricle and right atrium of your heart to help regulate the timing of contractions in the two chambers.

Biventricular pacemaker: biventricular pacemaker for those with heart failure and irregular heartbeats, biventricular pacing also known as cardiac resynchronization therapy is used. The right and left ventricles of the heart are both stimulated by this kind of pacemaker, which improves the heart's ability to beat

Reasons for Pacemaker Implantation

The majority of pacemakers are used to treat "bradycardia," or a sluggish heartbeat. The heart typically beats between 50 to 70 times per minute while at rest, and this pace can go up by two to three times while stressed or working out. A number of symptoms may appear if the heart beats too slowly because the brain and body do not receive enough blood flow [3]

METHODOLOGY

Each and every has some patterns and follows certain pathways in Oder to reach the destination. Thus the method to be followed plays an important role in determining in the output as well as consequences of the study

The study was organized into 4 steps to achieve the objectives

1. Type of study
2. Source of data
3. Regulatory requirements concerns
4. Study process

RESULTS

FDA's Role

- Oldest comprehensive consumer protection government agency
- Promote and protect health
- Covers foods, drugs, biologics, cosmetics, animal and veterinary medicine, and tobacco
- CDRH regulates medical devices and radiation emitting products

CDRH's Role

- Evaluate safety and effectiveness of medical devices

– Before and after reaching market

- Patients and providers have timely, continued access [4].

TYPES OF PREMARKET SUBMISSIONS

Premarket Submission Types

- Investigational Device Exemption (IDE)
- Premarket Notification (510(k))
- Premarket Approval Application (PMA)
- De Novo
- Humanitarian Device Exemption (HDE)

Investigational Device Exemption (IDE)

- Clinical research on investigational devices
- Collect safety and effectiveness data for future marketing application
- Requires approval by Institutional Review Board
- Protect human patients

Premarket Notification - 510(k)

- Market application for low and moderate risk device
- "Substantial Equivalence" between new device and a legally marketed device

Compare

- Intended use
- Device features
- Performance testing

Premarket Approval Application (PMA)

- Market application for highest risk devices
- Reasonable assurance: – safety and effectiveness
- Evidence stands on own – not equivalence

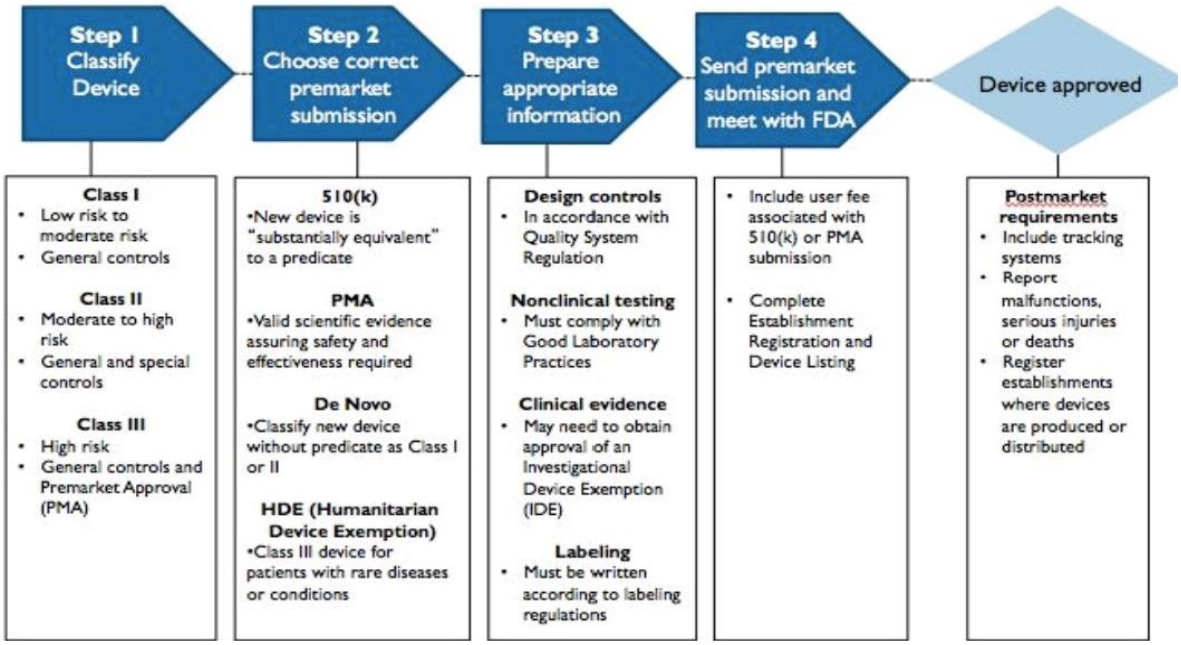
De Novo

- Device has no existing classification regulation
- Marketing process for novel devices
- Creates new classification regulation
- Alternative to PMA
- Reduced regulatory burden/controls based on risk benefit profile of device

Humanitarian Device Exemption HDE

- Premarket submission for Humanitarian Use Devices
- 8000 individuals per year in United States
- Exempt from effectiveness
- Reasonable assurance of safety and probable benefit [5].

FDA MEDICAL DEVICE APPROVAL PROCESS



FDA Action on a PMA

Within 180 days of the date of filing of the PMA (§814.40), FDA will complete its review of the PMA and of the advisory committee`s report and recommendation and issue one of the following:

- an approval order under §814.44(d),
- an approvable letter under §814.44(e),
- a not approvable letter under §814.44(f), or
- an order denying approval under §814.45

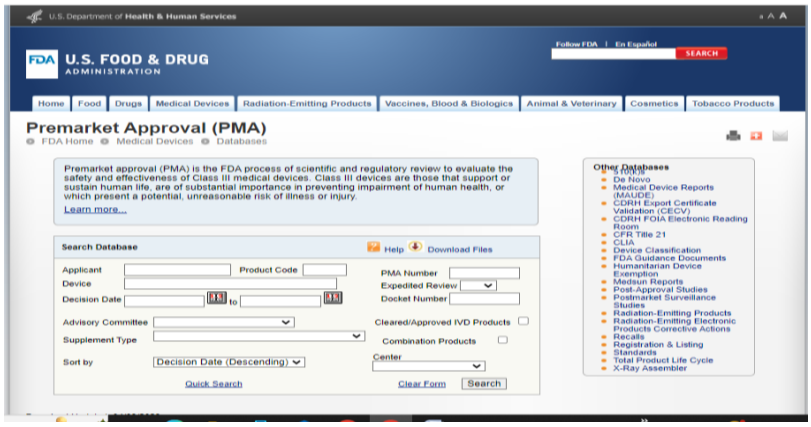


Figure1: PMA data base

Medical Device User Fee Amendments (MDUFA)
User Fees for FY2023

Annual Establishment Registration Fee: $6,493

Application Type	Standard Fee	Small Business Fee†
510(k)	$19,870	$4,967
513(g)	$5,961	$2,980
PMA	$441,547	$110,387
De Novo Classification Request	$132,464	$33,116

*† **Small Business Fee:** For businesses certified by the Center for Devices and Radiological Health (CDRH) as a small business [6].*
Table 2: Application Fees

DEVICE-I

Device: MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM
Generic name: Leadless Pacemaker
Regulation number: 870.3610
Applicant number: MEDTRONIC Inc.
8200coral Sea Street Ne
Ms Mv S11
Mounds View, MN 55112
PMA Number: P150033

Figure2: Medtronic Micra pacemaker

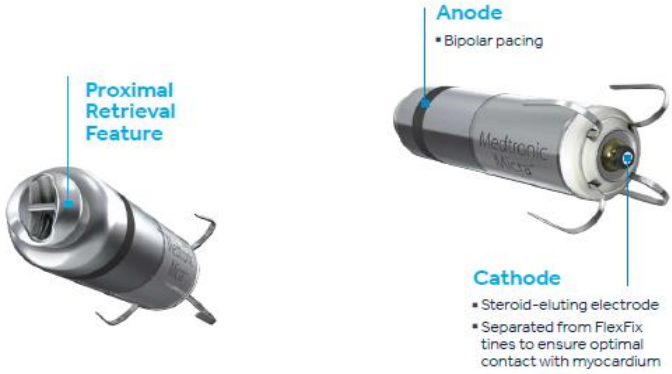


Figure3: anode and cathode of Medtronic Micra pacemaker

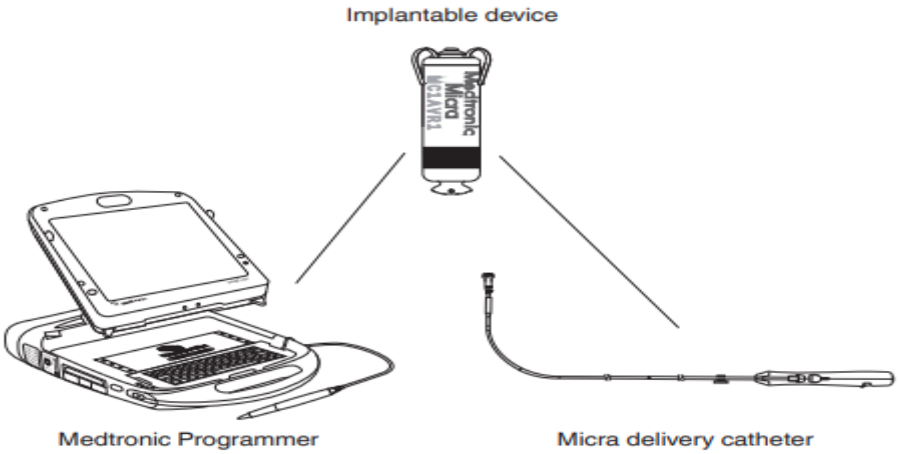


Figure 4: Implantable Medtronic Micra MC1AVR1

GENERAL INFORMATION

Device Generic Name: Implantable Cardiac Pacemaker (IPG)
Device Trade Name: Micra® Transcatheter Pacing System (Pacemaker Model MC1VR01 and Programmer Application Software Model SW022 Version 1.1)
The Medtronic Micra™ Model MC1VR01 single chamber implantable transcatheter pacing system (TPS) with SureScan™ technology (Medtronic, Inc., Mounds View, MN) is an MR (Magnetic Resonance) conditional programmable cardiac device that monitors and regulates the heart rate by providing rate-responsive bradycardia pacing to the right ventricle. The device senses the electrical activity of the heart, using the sensing and pacing electrodes on the titanium capsule of the device.
It monitors the heart rhythm for bradycardia and responds by providing pacing therapy, based on the pacing parameters programmed into the device. The device provides rate response, controlled through an activity-based sensor, and also provides diagnostic and monitoring information for guidance in the pacing system evaluation (14).
The Micra TPS contains a one inch-long, self-contained pacemaker that is implanted directly into the right ventricle chamber of the heart. It works like other pacemakers to control the heartbeat but, unlike other pacemakers, the Micra TPS does not have leads and does not require a subcutaneous pocket. The Micra TPS is a single-chamber pacing system, which paces only the right ventricle of the heart. The Micra TPS is implanted percutaneously directly into the heart via the femoral vein using a catheter delivery system and is attached to the right ventricle with four small nictinol prongs (tines). According to the Medtronic Clinician manual for the Micra TPS device:
Patients with an implanted Micra Model MC1VR01 pacing system can safely undergo an MRI scan provided the system meets the requirements described in the Medtronic MRI Technical Manual [7].

- **Less invasive** — Micra is placed in the heart via a vein in the leg. The procedure requires no chest incision and, unlike conventional pacemakers, does not create a scar or bump under the skin.
- **Self-contained** — Micra is completely self-contained within the heart. It eliminates potential medical complications arising from a chest incision and from wires running from a conventional pacemaker into the heart.
- **Small** — Micra is 93% smaller than conventional pacemakers, about the size of a large vitamin capsule

Brand	Medtronic
Longevity	10 years
Weight	1.75gm
Volume	0.8cc
MRI Compatible	Yes
Wireless	Yes
Application	Single Chamber

Table 3: overview of Medtronic Micra™ Pacemaker

INDICATION FOR USE

The Micra Transcatheter Pacing System is indicated for use in patients who have experienced one or more of the following conditions:

- Symptomatic paroxysmal or permanent high-grade AV block in the presence of Atrial Fibrillation (AF)
- Symptomatic paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy
- Symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy

Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity [8].

System components and accessories

Contents of sterile packaging: One implanted transcatheter pacing system, which includes the implantable device and delivery catheter system, is contained in the sterile package.

Ethylene oxide gas is used to disinfect the Micra AV transcatheter pacing device before it is placed in a pouch with a sterile aseptic tray. The tray is made to make it easier to install the pacemaker in the sterile zone. The pouch must not be harmed or opened in order for the pacing system to be sterile. The pouch's outside surfaces are non-sterile and should not be used in a sterile environment.

Implantable device: The Micra AV Model MC1AVR1 is a twin chamber transcatheter pacing system that offers bipolar sensing and pacing in the right ventricle in addition to AV synchronous pacing. In order to attach the device in the heart tissue at the implant position in the right ventricle, the device incorporates an active fixation mechanism made up of four electrically inactive tines.

MRI SureScan function

If the Micra AV Model MC1AVR1 pacing device a patient has implanted satisfies the specifications listed in the Micra AV Model MC1AVR1 MRI technical handbook, the patient may have an MRI scan. The patient may be securely scanned while the machine maintains the proper pacing thanks to the MRI SureScan pacing technology. For vital details on procedures and MRI-specific contraindications, warnings, and precautions

Device delivery catheter system – The Micra AV delivery catheter system consists of the following parts:

- A delivery catheter designed to carry, deliver, and position the device for implant in the right ventricle by accessing this chamber through the femoral vein. The delivery catheter has a steerable, flexible shaft with a rigid distal end that contains a device cup to hold the device and a recapture cone to retrieve it. The delivery catheter is compatible with a 7.8 mm (23 Fr) introducer sheath that is 56 cm (22 in) long or longer, such as the Medtronic Micra Introducer.
- A handle with controls to navigate the delivery catheter and deploy the device. The handle also provides a tether designed as an aid to test the device fixation and to recapture and reposition the device for proper fixation during the implant procedure

Programmer and software – The device is programmed for implant testing and patient follow-up appointments using a Medtronic programmer and software. The device and the programmer must communicate with the aid of a Medtronic programming head. Although they won't harm Medtronic devices, other manufacturers' programmers are incompatible with Medtronic devices [8].

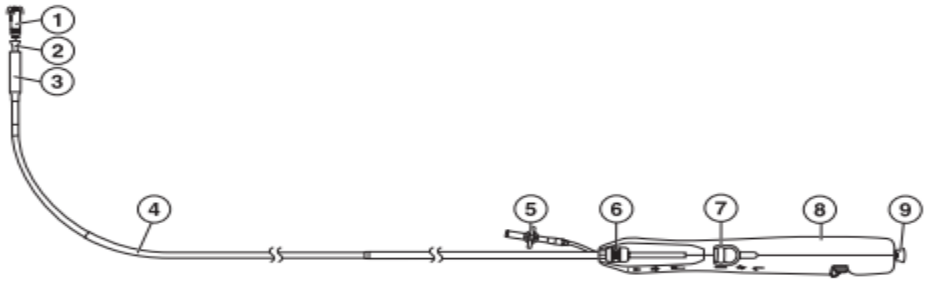
How to implant the device

Warning: The implant procedures in this section include the following potential hazards:

- Patient infection
- Acute tissue / vascular trauma
- Chronic trauma, including migration of product components
- Exposure to toxic materials
- Undesirable physiologic response

Note: Do not program the Rate Profile Optimization parameter to on before the implant procedure is completed.

This section describes how to prepare the delivery system and device for implant, insert the introducer into the patient's femoral vein, navigate the delivery system to the right ventricle, and deploy the device at the implant location

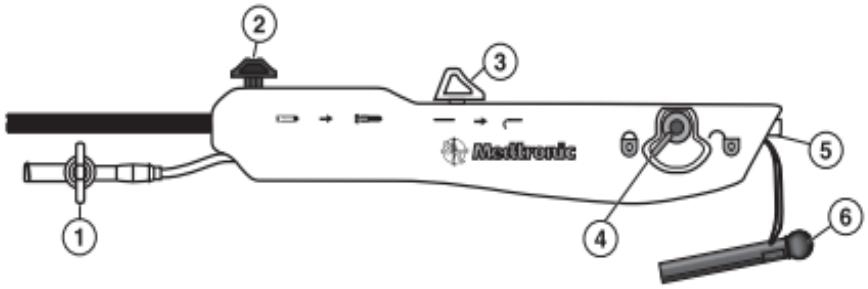


1 Micra AV device
2 Device recapture cone
3 Device cup
4 Delivery catheter
5 Flush port
6 Device deployment button
7 Catheter curve deflection button
8 Delivery system handle
9 Tether port

Figure5: Overview of the Micra AV transcatheter pacing system

1 Micra AV device capsule
2 Fixation tines
3 Pacing cathode
4 Pacing anode

Figure 6. The Micra AV device



1 Flush port
2 Device deployment button
3 Catheter curve deflection button
4 Tether lock button
5 Tether port
6 Tether retainer pin

Figure7: Micra AV delivery catheter system: deployment handle

1. Summary of Clinical Results

The Micra™ Transcatheter Pacing System (TPS) is a miniaturized single chamber pacemaker system that is delivered via catheter through the femoral vein and is implanted directly inside the right ventricle of the heart. The clinical study investigated the safety and efficacy of the Micra TPS at 6 months. Long-term device performance will be evaluated once all subjects have the opportunity to complete the 12- month follow-up visit.

2. Study Purpose

The purpose of the Micra™ TPS clinical study was to demonstrate safety and effectiveness of the Micra TPS and to assess long-term device performance.

3. Study Scope, Design, and Methods

The Micra TPS clinical study was a prospective, multi-site, single-arm worldwide Investigational Device Exemption (IDE) clinical study. The study was designed to have a continuously growing body of evidence, and data analyses were planned at various time points to evaluate the primary safety and efficacy objectives. The study utilized a group sequential analysis plan where the study's primary objectives could be evaluated at up to three time points shown in Figure 1. The primary safety objective of the study was to evaluate major complications related to the Micra system or procedure. The primary endpoint was evaluated at 6-months post-implant. The primary efficacy objective, Micra pacing capture thresholds, was also evaluated at 6-months post-implant. Both primary objectives were met at Analysis #1 after 300 subjects completed the 6-month visit, the results of which are presented in Section 6[9].

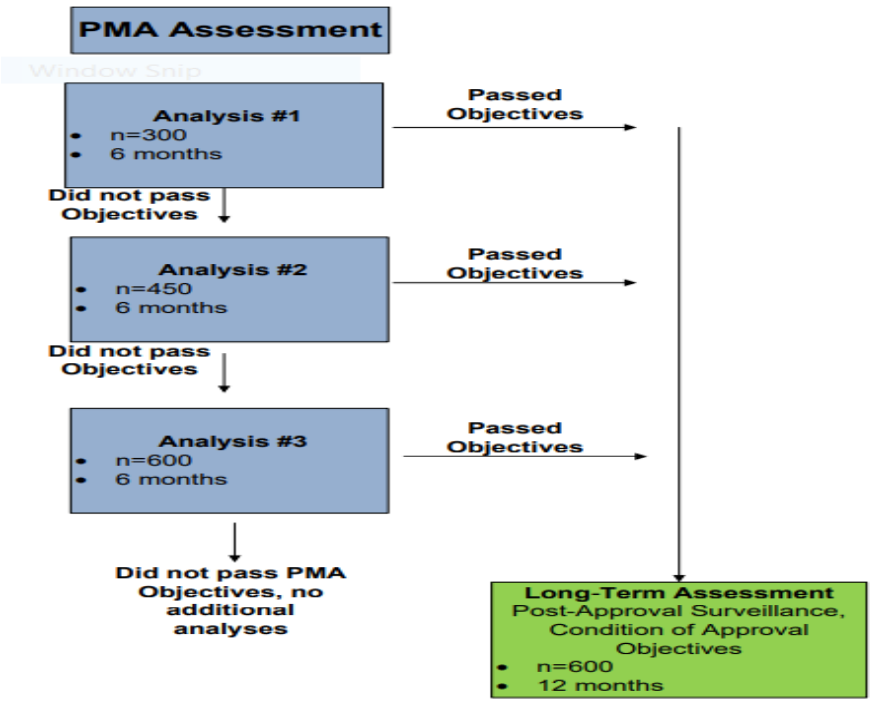


Figure8: Study analysis time points

Device Recall Medtronic Micra MC1VR01US
Recall number: Z-2492-2019
Recall event ID: 83547
Product classification: Leadless pacemaker
Product: Medtronic Micra MC1VR01, Single chamber transcatheter pacing system, REF MC1VR01US (US only) Cardiac pacemaker.
Manufacturer Reason for recall: Medtronic is updating the Micra Instructions for Use (IFU) and the Micra Implant Procedure Tip Card to include specific information on the removal of the tether to release the Micra Pacemaker from the Micra Delivery System during implant.
Action: In the US, beginning 06-Aug-2019, Medtronic Field Representatives are approved to provide the Instructions for Use Update Letter to physicians who have been trained to implant the Micra device as identified by Medtronic training records. Courtesy notifications to Risk Managers at accounts that have purchased Micra and Clinical Principal Investigators (PIs) at sites participating in clinical trials are also approved to be provided. The Instructions for Use Update letter will be sent via 2-day delivery beginning 12-Aug-2019 to the physicians and risk managers [10].
Distribution: Worldwide
Total Product Life Cycle (TPLC)

MDR YEAR	MDR REPORTS	MDR EVENTS
2018	656	656
2019	837	837
2020	1147	1147
2021	1479	1479
2022	1712	1712
2023	348	348

Table 4: TPLC of Medtronic pacemaker [11]

DEVICE- II

GENERAL INFORMATION

Device Generic Name: VR Leadless Pacing System; Implantable pacemaker pulse generator Device Trade Name: Aveir™ VR Leadless System

- Aveir™ Leadless Pacemaker (Right Ventricular)
- Aveir™ Delivery System Catheter
- Aveir™ Link Module

Premarket Approval Application (PMA) Number: P150035
Date of FDA Notice of Approval: March 31, 2022

INDICATIONS FOR USE

The Aveir™ Leadless Pacemaker is indicated for patients with bradycardia and:

- Normal sinus rhythm with only rare episodes of A-V block or sinus arrest
- Chronic atrial fibrillation
- Severe physical disability

Figure9: Aveir Leadless Pacemaker

DEVICE DESCRIPTION

Aveir™ Leadless System: The Aveir™ Leadless System contains the following components:

- Aveir™ Leadless Pacemaker (LSP112V)
- Aveir™ Delivery System Catheter (LSCD111)
- Aveir™ Link Module (Model LSL02)

Aveir Leadless Pacemaker (Model LSP112V) The Aveir™ Leadless Pacemaker (LP) System provides bradycardia pacing as a pulse generator with built-in battery and electrodes, for implantation in the right ventricle. The Aveir Leadless Pacemaker is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy to the target population. As a leadless device, it does not need a connector, pacing lead, or pulse generator pocket [12].
A distal no retractable helix affixes the LP to the endocardium. The tip electrode includes a single dose of dexamethasone sodium phosphate (DSP), intended to reduce inflammation. Three additional features on the outside of the LP nosecone are designed to provide secondary fixation securement. Sensing and pacing occur between a distal electrode near the helix and the external can of the LP. The LP's proximal end has a feature for docking to delivery and retrieval catheters, providing for repositioning and retrieval capability. The LP communicates bi-directionally with the programmer system via electrical signals conducted between the implanted LP's electrodes and skin electrodes applied to the patient's chest and connected to the programmer system. Consequently, the LP transmits signals using circuits and electrodes already provided for pacing, with data encoded in pulses delivered during the refractory period of the ventricle. The LP senses right ventricular blood temperature to provide an increase in pacing rate with increased metabolic demand [12]
Aveir Delivery Catheter (Model LSCD111) The Aveir Delivery Catheter includes a steerable delivery catheter, an integrated guiding catheter with a protective sleeve designed to protect an attached LP's fixation helix and electrode, and a valve bypass tool to dilate the 25Fr inner diameter Introducer sheath haemostasis valve and advance the system into the femoral vein.

Figure10: Aveir Delivery Catheter

Aveir Link Module (Model LSL02)
The Aveir Link Module communicates with an implanted Aveir Leadless Pacemaker via conducted communication through the patient cable and skin electrodes. Safe, high frequency electrical pulses are sent between the LP and programmer system to program and interrogate the Aveir Leadless Pacemaker. The Link Module also uses the patient cable and skin electrodes to acquire a patient's ECG waveform The Link Module is powered via USB port of the Merlin Patient Care System Model 3650[12].

Figure11: Aveir Link Module

MRI safety information
A Magnetic Resonance Imaging (MRI) scanner is a large machine that can create images of the soft tissues inside the body. This tool is very helpful in diagnosing many problems; but, to create the MR image the scanner must generate very strong magnetic forces that can be very dangerous to almost all implanted devices, like pacemaker. The magnetic fields can interfere with the tiny computer in pacemaker. The Aveir™ leadless pacemaker, however, was specially designed to withstand the fields of most MRI scanners. Because it is an MR Conditional device, can safely have an MRI scan under certain conditions [12].
Leadless Pacemaker
A small implantable device that sends electrical pulses to the heart whenever it senses that the heartbeat is too slow A leadless pacemaker is placed directly in the heart without the need for a surgical pocket and insulation wires (called leads)[13].

CDRH DECISION

CDRH issued an approval order on March 31, 2022. The final clinical conditions of approval cited in the approval order are described below.
This study will be conducted as per protocol dated August 27, 2021, Version A. The purpose of this post-approval study (PAS) is to evaluate the long-term safety of the single-chamber Aveir™ Leadless Pacemaker device (VR LP) using real world evidence methods. A sample size of 2,100 patients is required to provide estimates of adverse events to a specific resolution with confidence intervals. All patients who had an implant of the Aveir VR LP device, met inclusion/exclusion criteria, and have linked to Medicare FFS claims will be included in the analysis of this endpoint. Acute and long-term safety of the Aveir™ VR LP will be evaluated in terms of 30-day and 10-year post implant complication-free rates. The frequency of PAS reports is every 6 months for the first two years and yearly thereafter [14].

Brand	Aveir
Longevity	10.3 years
Weight	3.0gm
Volume	1.4 cc
MRI Compatible	Yes
Wireless	Yes
Application	Dual Chamber

Table 5: overview **of AVEIR VR Leadless Pacemaker**

HOW THE AVEIR VR LEADLESS PACEMAKER IS IMPLANTED

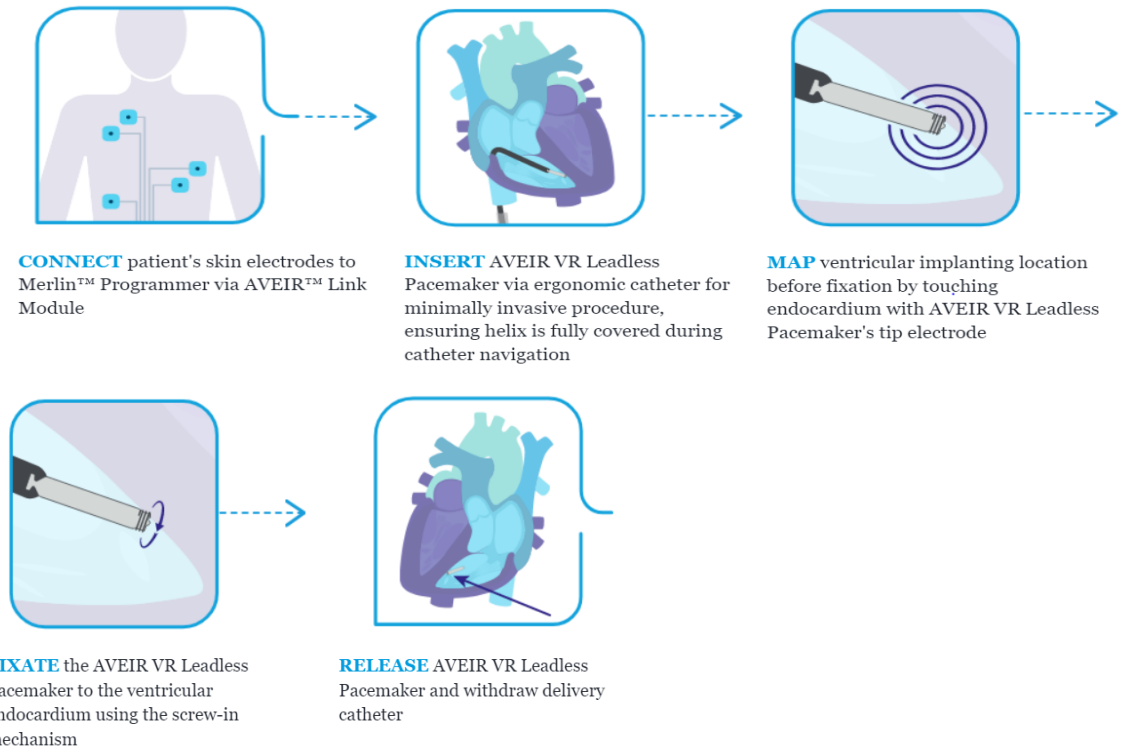


Figure 12: Implanting AVIER RVR Pacemaker [15]

Medical Product Safety Information

MedWatch is the FDA's portal for information on clinically significant safety issues and reporting grave issues with human medical products.

When it comes to human medicines, medical devices, vaccines and other biologics, nutritional supplements, and cosmetics, MedWatch alerts offer timely new safety information. The alerts include useful information that can improve the treatment and diagnostic decisions made by patients and healthcare professionals [16].

Voluntary Reporting for Use by Health Professionals, Consumers, and Patients

Reporting can be done through our online reporting portal or by downloading, completing and then submitting FDA Form 3500 (health professional) or 3500B (consumer/patient) to MedWatch: The FDA Safety Information and Adverse Event Reporting Program

MedSun: Medical Product Safety Network

MedSun: Shining a Light on Medical Product Safety

The U.S. Food and Drug Administration's Center for Devices and Radiological Health (CDRH) launched the Medical Product Safety Network (MedSun), an adverse event reporting platform, in 2002. Working cooperatively with the clinical community to recognize, comprehend, and address issues related to the use of medical devices is the core motive of MedSun [17].

How MedSun Works

Participants use an Internet-based system that is designed to be an easy and secure way to report adverse medical device events. Each facility has online access to the reports they submit to MedSun so that they can be tracked and reviewed at any time.

Difference between MedWatch and MedSun

Mandatory MDR	MedWatch	MedSun
Reporter must wait for FDA to contact them to know who is reviewing the report	Reporter must wait for FDA to contact them to know who is reviewing the report	Clinical site has designated point of contact at FDA that reviews all reports from that facility
Mandatory reporting	Voluntary reporting	Mandatory reporting required, and participants also agree to send voluntary reports
Paper and electronic reporting formats	Paper and electronic reporting formats	Electronic reporting format
Manufacturer, importer, and user facility reporting	Consumer and healthcare professional reporting (and any interested person)	User facility reporting only (250 designated sites)
Public may search MDR, MedWatch, and MedSun reports at	Public may search MDR, MedWatch, and MedSun reports at http:// www.accessdata.fda.gov/scripts/cdrh/ cfdocs/cfmaude/textsearch.cfm	Public may search MedSun reports at http://fda.gov/medsun
Participation is mandated by regulation (CFR 21, Part 803)	Participation is voluntary	Participation is by invitation only

Table6: Medical Device Report Comparison

Risks

Although pacemaker-related complications are rare, they could arise and include the following:

- An infection close to the heart's implanted device site
- Bruising, bleeding, or swelling at the pacemaker site, particularly if you take blood thinners
- Clots in the blood (thromboembolism) close to the pacemaker site blood vessel or nerve damage close to the pacemaker
- compromised lung (pneumothorax)
- Blood between the lung and the chest wall (hemothorax)
- Device or lead movement (moving) that could cause cardiac perforation (rare) [18].

The U.S. Food and Drug Administration (FDA) is warning medical professionals about the potential for serious problems if a heart perforation develops during the implantation of a leadless pacemaker. An uncommon consequence of any pacemaker device implant is cardiac perforation. Severe problems or even death may result from cardiac perforation.

The total risk of myocardial perforation associated with the installation of a leadless pacemaker resembles that of conventional transvenouspacing systems.

FDA Actions

The FDA is working with the manufacturer to evaluate outcomes after cardiac perforation following implantation of leadless pacemaker systems to identify potential contributing factors and mitigation measures, and to ensure the product labeling adequately addresses the issue. The FDA will continue to monitor reports of adverse events and other sources of post market data associated with leadless pacemaker systems and will update the public if new or additional information becomes available [19].

Reporting Problems to the FDA

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program
- Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations.

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities [19].

CONCLUSION

Technology has a significant impact on every aspect of our life, and a new trend favours the use of commercial smart wearable devices to regulate life quality. As medical devices become more interconnected with one another, the Internet, hospital networks, and other technologies, features that improve patient care and the ability of healthcare personnel to deliver it are made possible. There is tremendous potential to alter cardiovascular prevention and management strategies in order to enhance health outcomes and lessen the financial burden of cardiovascular events as a result of the expanding availability of a wide range of linked health devices. A common metric for assessing a community's general health is life expectancy. Age-specific health is measured by life expectancy at birth. Trends in mortality are frequently described by changes in life expectancy. A pacemaker lifestyle Pacemakers typically last between five and seven years, depending on usage and the type of device. The device's durability has significantly increased in recent years. A pacemaker's normal lifespan might range from five to fifteen years. Medical technology enables early and accurate diagnosis of health conditions, enabling fast interventions and better outcomes.

FUTURE SCOPE

The future scope of cardiac devices look bright but incorporation and adoption of new technologies remains a challenge. Wearable technologies provide the possibility of continuous rhythm monitoring.

ACKNOWLEDGEMENTS

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DECLARATION OF CONFLICTING INTERESTS

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