Check Your AED: Is it FDA Approved?

Here's what the FDA wants you to know**

The FDA published a final order in February 2015 requiring premarket approval (PMA) applications for new and existing AEDs and necessary AED accessories. Manufacturers of all necessary AED accessories, such as batteries, electrode pads, adapters and hardware keys for pediatric use, must file a PMA by February 3, 2020. If a PMA is not filed by February 3, 2020, the manufacturer must cease marketing their accessories by February 3, 2021.

There are now FDA-approved AEDs available, and we encourage you to ensure your AED is FDA-approved; if it is not, we encourage you to begin making plans to transition to an FDA-approved AED.

If you or your Organization own(s) an AED device, the FDA recommends you:

- Check the table to see if your AED is FDA-approved. Contact the manufacturer of your AED if you are not sure if your AED is FDA-approved
- Contact the manufacturer of your AED if your AED is not FDA-approved and you have not received a letter about your AED
- Be aware that if your AED is not FDA-approved, compatible necessary AED accessories may no longer be available to support your AED after February 3, 2021
- Contact the manufacturer of your AED or AED accessories for information specific to your product
- Given the importance of these devices in emergency situations, the FDA recommends you continue to keep your AED available for use until you receive an FDA- approved AED
- Report problems with AEDs to the FDA by submitting a voluntary report online at MedWatch

Can't find your device listed here?
A Cardiac Science AED Specialist can help!
To learn more visit:

www.cardiacscience.com/us-sales-representatives/

Check this list to see if your AED is approved by the FDA**

Manufacturer	Device Name	AED Type	Approval Date	Premarket Database
Cardiac Science Corporation	Powerheart® G3 AED	Public Access	12/07/2018	P160033
Cardiac Science Corporation	Powerheart® G3 Plus AED	Public Access	12/07/2018	P160033
Cardiac Science Corporation	Powerheart® G5 AED	Public Access	12/07/2018	P160033
Cardiac Science Corporation	Powerheart® G3 Pro AED	Professional Use	12/06/2018	P160034
ZOLL Medical Corporation	AED Plus and Fully Automatic AED Plus	Public Access	05/26/2017	P160015
ZOLL Medical Corporation	X Series Defibrillator	Professional Use	12/27/2017	P160022
ZOLL Medical Corporation	R Series Defibrillator	Professional Use	12/27/2017	P160022
ZOLL Medical Corporation	AED Pro Defibrillator	Professional Use	12/27/2017	P160022
ZOLL Medical Corporation	AED 3 BLS Defibrillator	Professional Use	12/27/2017	P160022
Defibtech, LLC	Lifeline/ReviveR DDU-100	Public Access	02/01/2018	P160032
Defibtech, LLC	Lifeline/ReviveR AUTO DDU-120	Public Access	02/01/2018	P160032
Defibtech, LLC	Lifeline/ReviveR VIEW DDU-2300	Public Access	02/01/2018	P160032
Defibtech, LLC	Lifeline/ReviveR VIEW AUTO DDU-2200	Public Access	02/01/2018	P160032
Defibtech, LLC	Lifeline/ReviveR ECG DDU-2450	Public Access	02/01/2018	P160032
Defibtech, LLC	Lifeline/ReviveR ECG+ DDU-2475	Public Access	02/01/2018	P160032
HeartSine Technologies, LLC	SAM 350P (Samaritan Public Access Automated External Defibrillator)	Public Access	01/12/2017	P160008
HeartSine Technologies, LLC	SAM 360P (Samaritan Public Access Automated External Defibrillator)	Public Access	01/12/2017	P160008
HeartSine Technologies, LLC	SAM 450P (Samaritan Public Access Automated External Defibrillator)	Public Access	01/12/2017	P160008
Philips Medical Systems	HeartStart Home	Home Use	06/06/2019	P160029
Philips Medical Systems	HeartStart OnSite	Public Access	06/06/2019	P160029
Philips Medical Systems	HeartStart FR3	Public Access	* See note	* See note
Philips Medical Systems	HeartStart FRx	Public Access	* See note	* See note
Physio-Control, Inc.	LIFEPAK CR Plus Defibrillator	Public Access	12/21/2017	P160012
Physio-Control, Inc.	LIFEPAK EXPRESS Defibrillator	Public Access	12/21/2017	P160012
Physio-Control, Inc.	LIFEPAK CR2 Defibrillator	Public Access	12/21/2018	P170018
Physio-Control, Inc.	LIFEPAK 15 Monitor/Defibrillator	Professional Use	07/02/2018	P160026
Physio-Control, Inc.	LIFEPAK 20E Defibrillator/ Monitor	Professional Use	07/02/2018	P160026
Physio-Control, Inc.	LIFEPAK 1000 Defibrillator	Professional Use	07/02/2018	P160026

* PMA is approvable subject to an FDA inspection that finds the manufacturing facilities, methods, and controls in compliance with the applicable requirements of the Quality System regulation (21 CFR Part 820)

** https://www.fda.gov/medical-devices/cardiovascular-devices/automated-external-defibrillators-aeds

Visit **cardiacscience.com/FDAapproved** for additional information