



Is your AED approved by the FDA?

ZOLL® is here to support your transition to an FDA-approved monitor/defibrillator.

What the FDA wants you to know:

To help ensure the quality and reliability of automated external defibrillators (AEDs), the FDA has established more stringent regulatory requirements. The FDA published a final order in February 2015 requiring premarket approval (PMA) applications for new and existing AEDs and AED accessories. If your AED is not FDA-approved, the accessories necessary for your AED may no longer be supported by the manufacturer, and thus will no longer be available after **February 3, 2021**.

What this means to you:

To ensure the availability of lifesaving treatment with the AEDs in your facilities, we encourage you to determine whether your AED is FDA-approved, and if it is not, to begin making plans to transition to an FDA-approved AED.

If your AED is **not FDA-approved**, the accessories necessary for your AED may no longer be supported by the manufacturer and will not be available after February 3, 2021.

If the manufacturer **HAS FILED for PMA** (or has already received approval), those AEDs and related accessories will continue to be available. You do not need to replace them.

The FDA recommends that you take the following steps:

- Determine the brand and model of your AED. Most AEDs indicate the brand and model on the back of the device. In some cases it is also printed on the front.
- To see if your AED is FDA-approved, check the list on this document or on [FDA.gov](https://www.fda.gov).
- If your AED is not listed, plan to transition to an FDA-approved AED by February 3, 2021.
- Given the importance of these devices in emergency situations, the FDA recommends that you continue to keep your AED available for use until you obtain an FDA-approved AED.

FDA-Approved Automated External Defibrillators (AEDs)

Manufacturer	Device Name and Model Number
Cardiac Science	Powerheart G3 (model 9300) Powerheart G3 Plus (model 9390) Powerheart G5 (all models) Powerheart G3 Pro
Defibtech	Lifeline/Reviver (DDU-100/DDU-120) Lifeline/Reviver View (DDU-2200/DDU-2300) Lifeline/Reviver ECG (DDU-2450/DDU-2475)
Heartsine Technologies (Stryker)	Samaritan SAM 350P Samaritan SAM 360P Samaritan SAM 450P
Philips Medical	HeartStart Home HeartStart Onsite
Physio-Control (Stryker)	LifePak CR Plus (all models) LifePak Express LifePak CR 2 (all models) LifePak 1000 (all models)
ZOLL Medical	AED Plus (all models) AED Pro (all models) ZOLL AED 3 BLS

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

If you're unsure if your AED is impacted by this FDA order, contact ZOLL's distributor support department at (888) 851-8584 and we'll gladly assist you.