Frequently Asked Questions

**Question**
What is the final order requiring premarket approval (PMA) from the U.S. Food and Drug Administration (FDA)?

**Answer**
Over the past several years, the FDA has increased its focus on ensuring that AEDs and professional defibrillators are safe and reliable. As part of this focus, the FDA has modified the approval process for these devices from the previous 510k approval to the more stringent PMA process.

From the FDA, effective April 2019:

> “The FDA sent letters to all AED manufacturers who did not submit a premarket approval (PMA) application for their AEDs as required by the final order, reminding them they can no longer market their AED; the letters also informed the manufacturers that necessary AED accessories may not be marketed if a PMA is not filed. Manufacturers were asked to provide a plan for these AEDs and necessary AED accessories, including a timeline for servicing and phase-out activities, a plan for communicating with their customers, and an estimate of the volume of AEDs and accessories that remain in the field.”

The FDA announced that accessories (including, but not limited to, batteries, cables, hardware, and therapy electrodes) and service for any defibrillator that is not FDA-approved under premarket approval (PMA) will **no longer be available for sale** after February 3, 2022. This applies to all defibrillator manufacturers and distributors in the United States.

**Question**
Has the COVID-19 pandemic affected the PMA timeline?

**Answer**
Yes, the FDA has extended the deadline that manufactures and distributors can offer accessories and services for devices that are not premarket approved to February 3, 2022. This reflects a one-year extension from the originally announced date of February 3, 2021.
**Question**
Which ZOLL® defibrillators carry FDA premarket approval (PMA)?

**Answer**
- AED Plus® defibrillator
- Fully Automatic AED Plus defibrillator
- AED Pro® defibrillator
- ZOLL AED 3® BLS defibrillator
- R Series® monitor/defibrillator
- X Series® monitor/defibrillator
- Propaq® MD monitor/defibrillator

**Question**
Which ZOLL defibrillators do not carry FDA premarket approval (PMA)?

**Answer**
The ZOLL M Series® and ZOLL E Series® monitor/defibrillators are not FDA-approved under PMA. In 2012, sales of both the M Series and E Series monitor/defibrillators were discontinued and accordingly, no PMA application was filed with the FDA. The FDA recommends that defibrillator owners/users of non-approved devices begin making plans to transition to an FDA-approved defibrillator – see above for a list of ZOLL FDA-approved devices.

**Question**
Will service and accessories be available for the M Series and E Series through February 3, 2022?

**Answer**
ZOLL will continue to support the M Series and E Series monitor/defibrillators as parts availability allows. Procurement of replacement parts is limited and as a result this may affect product service offerings. In accordance with previous announcements, the M Series replacement battery and EtCO₂ sensor are no longer being manufactured.
**Question**
Where can I get more information?

**Answer**
Visit the [FDA website](https://www.fda.gov) for up-to-date information and a complete list of FDA-approved devices.

For information on upgrade and financing options to support you during this transition:

- Contact your local [ZOLL sales representative](https://www.zoll.com) or authorized distributor
- Call ZOLL Customer Service at 800-348-9011
- Submit the [PMA Information Request Form](https://www.zoll.com)