TOP 5 THINGS TO KNOW
ABOUT THE NEW FDA PMA REGULATION

1 What is **PMA?**

PMA, or premarket approval, is the FDA's regulatory review process, designed to ensure the safety and effectiveness of medical devices. The FDA recently announced that accessories and service for any defibrillator that is not approved under PMA will no longer be available after **February 3, 2022.**

2 Which ZOLL defibrillators **are not FDA-approved?**

The ZOLL M Series® and E Series® monitor/defibrillators are not FDA-approved under PMA. In 2012 and 2015, respectively, ZOLL discontinued these devices, and therefore no PMA application was filed.

3 Which ZOLL defibrillators **are FDA-approved?**

- AED Plus®, AED Pro®, ZOLL AED 3® and ZOLL AED 3 BLS
- Powerheart® G3 and Powerheart® G5
- R Series®
- X Series®

PMA FDA-APPROVED

4 How does **PMA affect me?**

All defibrillators need to be FDA-approved by the above date. Take inventory of your AED and professional defibrillator fleet and check them against the FDA-approved devices list: **You can find this list at www.fda.gov/medical-devices/cardiovascular-devices/automated-external-defibrillators-aeds.**

If any of your devices are not on the FDA-approved AED list, ZOLL can help you discover information and learn what steps are next in transitioning to FDA-approved products.

5 Where can I **find more information** about transitioning to FDA-approved devices?

ZOLL is offering several upgrade programs in order to meet all of our customer needs.

Visit us at zoll.com/PMA or call us at 800-804-4356 to learn more about how we can help you make the transition.

MCN PP 2006 0467

ZOLL®