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FDA/CDRH Webinar

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Overview of the Final Order calling for PMAs for AEDs

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Purpose

The purpose of this webinar is to provide an overview of the final order focusing on what is expected from AED device and accessory manufacturers for premarket approval submissions

Agenda

- Overview of the Final Order
- New devices or accessories
- AED devices currently distributed
- AED accessories currently distributed
- Next steps

Final Order Summary

The Food and Drug Administration is issuing a final order to require the filing of premarket approval applications (PMA) for automated external defibrillator (AED) systems, which consist of an AED and those AED accessories necessary for the AED to detect and interpret an electrocardiogram and deliver an electrical shock.

- http://www.gpo.gov/fdsys/pkg/FR-2015-02-03/pdf/2015-02049.pdf

Final Order Overview

- **What is included in the order:**
  - AED device
  - Necessary AED accessories such as:
    - Pad electrode
    - Battery
    - Adapter
    - Hardware key for pediatric use

Final Order Overview

- **What does this mean?**
  - All new devices and accessories require a PMA approval prior to beginning distribution.
  - In order to continue to distribute AED devices that were cleared through the 510(k) process, an Intent to File and a PMA is required to be submitted within the timeline specified in the order.
  - In order to continue to distribute necessary AED accessories that were cleared through the 510(k) process, a PMA is required to be submitted within the timeline specified in the order.

New Devices

- **Devices for which a 510(k) clearance was not issued**
  - Must receive a PMA approval before the device can be legally marketed.
- **Accessories for which a 510(k) clearance was not issued**
  - Must receive a PMA approval before the device can be legally marketed.

Currently Marketed AED devices

- **Intent to File**
  - Must be submitted within 90 days from the date of the final order.
  - Provided formally to the agency.
  - Must include a list of all devices (including model numbers and 510(k) numbers) for which a PMA will be sought
  - Intent to file is only needed for currently marketed AED devices (not needed for accessories).
  - For specific models of devices identified in the intent to file for which a PMA will be submitted, distribution of those models can continue until a PMA is submitted but not longer than 18 months from the date of the final order.
  - For devices for which an Intent to File will not be submitted, distribution must stop within 90 days from the date of the final order.

Currently Marketed AED devices cont.

- **PMA**
  - For devices identified in the Intent to File, the PMA must be submitted within 18 months from the date of the final order.
  - Multiple Public Access devices may be submitted in a single PMA.
  - Multiple Professional devices may be submitted in a single PMA.
  - Necessary accessories may be submitted within the PMA for the AED device.
  - For devices included in the PMA, distribution can continue while PMA is under review. Distribution will need to cease if a not approvable or denial decision is issued.

Currently Marketed AED devices cont.

If a notice of intent to file a PMA for a currently marketed AED device is not submitted within 90 days of the effective date of the final order or a PMA is not approved, then the manufacturer must cease distribution or the device will be deemed to be adulterated within the meaning of section 501(f)(1)(A) of the FD&C Act (21 U.S.C. 351(f)(1)(A)), and subject to seizure and condemnation under section 304 of the FD&C Act (21 U.S.C. 334) if its distribution continues.

Currently Marketed AED accessories

- **PMA**
  - If not included in the AED device PMA, a separate PMA must be submitted within 5 years from the date of the final order.
  - For devices included in a PMA (either a separate PMA or as part of the AED device PMA), distribution can continue while PMA is under review. Distribution will need to cease if a not approvable or denial decision is issued.

Timeline - Summary

Currently Marketed Devices and Accessories

- **Currently Marketed AED devices and accessories**

	Timetable for Which FDA Does Not Intend to Enforce Compliance (days or months after effective date of order)	Distribution Period (months after effective date of order)
Intent to File a PMA	AEDs - 90 days Accessories (N/A)	AEDs included in an intent to file: 18 months AEDs not included in intent to file: 90 days
File a PMA	AEDs- 18 months Accessories -60 months	Until a not approvable decision or denial decision letter is issued; can continue distribution if an approval order is issued.

Next Steps

- **Manufacturers**
  - File Intent to file for existing devices (AED devices only) followed by PMA (within 18 months of the date of the order)
  - For those accessories that you intend to continue to market, file a PMA (within 5 years of the date of the order)
  - File a PMA for any new devices or accessories
  - Use pre-submission process to obtain specific feedback from the agency.
- **Device Users**
  - Continue to use devices as needed
  - Continue to maintain devices per manufacturers instructions

Questions?

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