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AED product discontinuation FAQs

HeartSine® AEDs

For products marketed in the U.S.

Q: Which HeartSine devices were addressed in Stryker's product discontinuation notice dated October 30, 2020?

A: HeartSine samaritan® AED, HeartSine samaritan PAD 300 (SAM 300), and HeartSine samaritan PAD 300P (SAM 300P) automated external defibrillators.

Q: How is this notice different than the one issued in September 2019?

A: This notice extends the deadline when the Pad-Pak™ will not be available for use with the HeartSine SAM 300 or SAM 300P and the Pediatric-Pak™ will not be available for use with the HeartSine SAM 300P from February 3, 2021 to **February 3, 2022**, based on updated guidance from FDA in May 2020 due to the COVID-19 pandemic.

Q: What was communicated in Stryker's most recent HeartSine customer letter dated October 30, 2020?

A: While the Pad-Pak™ and Pediatric-Pak™ will continue to be available for use with the HeartSine SAM 350P, SAM 360P, and SAM 450P devices, the Pad-Pak and Pediatric-Pak are not PMA approved for use with the SAM 300 or SAM 300P; therefore the Pad-Pak will not be available for use with the SAM 300 or SAM 300P and the Pediatric-Pak will not be available for use with SAM 300P after **February 3,2022**.

The FDA requires AED manufacturers to ensure customers who previously purchased the HeartSine samaritan AED, SAM 300, and SAM 300P are aware of the PMA requirement and the need to transition to a PMA-approved AED in a timely manner.

Q: What is driving the **February 3, 2022** date?

A: In April 2019, the FDA communicated regarding the final order requiring premarket approval (PMA) applications for new and existing AEDs and necessary AED accessories:

> *"In 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 manufactures that necessary AED accessories may not be marketed after February 3, 2020, 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."**

In September 2019, the FDA updated the deadline for marketing AED accessories to no later than February 3, 2021 to allow customers adequate time to transition to PMA approved AEDs:

> *"Manufacturers of necessary AED accessories (such as batteries, pad electrodes, adaptors and hardware keys for pediatric use) for AED systems that are not FDA-approved may market their AED accessories until February 3, 2021."**

Emergency Care
11811 Willows Road NE, Redmond, WA 98052 USA | P +1 425 867 4000 | Toll-free +1 800 442 1142 | stryker.com

In October 2020, due to the COVID-19 pandemic, the FDA updated the deadline on their website for marketing AED accessories to no later than February 3, 2022 to allow customers adequate time to transition to PMA approved AEDs:

> *"Previously, FDA communicated that manufacturer distribution and marketing of necessary AED accessories must cease by February 3, 2021. However, due to the COVID-19 pandemic, FDA has determined that additional time may be needed for healthcare facilities to transition to FDA-approved AEDs. Therefore, FDA does not intend to object to the distribution of necessary AED accessories (such as batteries, pad electrodes, adaptors and hardware keys for pediatric use) for legacy AED systems until February 3, 2022. This will allow manufacturers to distribute their necessary AED accessories to support legacy AEDs due to the potential burden on healthcare facilities to transition to FDA-approved AEDs during this time."*

Q: Who do I contact with any questions?

A: Please contact your local Stryker sales representative or authorized distributor to discuss trade-in and flexible financing options to support you during this transition. You may also contact Stryker Customer Service at (800) 442-1142, option 2.

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