Provider Newsflash
August 2024

FDA Recall – Smiths Medical

Purpose of this communication:

- We are writing to inform you that the FDA has issued notice of a Class I Recall by Smiths Medical for correction of the software for their CADD-Solis and CADD-Solis VIP Ambulatory Infusion Pumps due to multiple issues that may occur when using pumps with software versions before version V4.3. Use of the affected products may cause adverse health consequences related to delay, interruption, under or over-administration of therapy or death. This recall involves correcting the certain devices and does not include removing them from where they are used or sold.

What do I need to do?

- Please review the following recall notice: Ambulatory Infusion Pump Software Correction: Smiths Medical Issues Correction for CADD-Solis and CADD-Solis VIP Ambulatory Infusion Pump Software due to Multiple Issues Related to Outdated Software | FDA
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.

EDRC# 1604. 092021