Class 2 Device Recall CSA Medical truFreeze Spray Kit

Date Posted: April 23, 2015
Recall Status: Open
Recall Number: Z-1513-2015
Recall Event ID: 70851
Premarket Notification 510(K) Number: K143625
Product Classification: Carrier, Liquid - Product Code GEJ
Product: CSA Medical truFreeze Console - Cryosurgical Unit Cryogenic Surgical Device Model: CC3-01
Code Information: Serial Numbers: 01-00106 through 01-00201
Recalling Firm/Manufacturer: CSA Medical
Manufacturer Address: 91 Hartwell Ave
Lexington, Massachusetts 02421-3137
Manufacturer Reason for Recall: TruFreeze Console caused a higher rate of liquid nitrogen (cryogen) to be delivered and may cause: stricture, scarring, bradycardia, or pneumothorax
FDA Determined Cause: DESIGN: Software Design

Action:
CSA Medical issued letter dated 3/25/15 advising users of the problem. Users provided with: The mitigations available to the active venting procedures coupled with the extremely unlikely probability of injury, rare risk, thus allowing the physician to continue with active venting procedures. In regards a passive venting procedure may not have sufficient mitigation to allow the physician to identify the potential hazard with sufficient time to preclude a potential for injury. Therefore, passive users will be instructed not to use the system until a software improvement is put into place. Additionally, no catheters or consoles will be shipped to passive venting users of truFreeze. A response form to sign and returned confirming receipt of the notification. Questions contact: Stephen Mascoli, MD 781-538-4755 smascoli@csamedical.com.

Quantity in Commerce: 82 units
Distribution: Nationwide
Total Product Life Cycle: TPLC Device Report

510(K) Database: 510(K)s with Product Code = GEJ and Original Applicant = CSA MEDICAL, INC.

Links on this page: