Class 2 Recall
CSA Medical truFreeze Spray Kit

See Related Information[23]

Date Posted	April 23, 2015
Recall Status[1]	Open
Recall Number	Z-1513-2015
Recall Event ID	70851[24]
Premarket Notification 510(K) Number	K143625[25]
Product Classification	Carrier, Ligature[26] - **Product Code** GEJ[27]
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 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 [2]	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 be signed and returned confirming receipt of the notification.Questions contact: Stephen Mascioli, MD 781-538-4755 smascioli@csamedical.com.
Quantity in Commerce	82 units
Distribution	Nationwide
Total Product Life Cycle	TPLC Device Report[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = GEJ and Original Applicant = CSA MEDICAL, INC.[30]

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1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain