Class 2 Recall Fresenius Crit Line

See Related Information[22]

Date Posted	February 03, 2015
Recall Status[1]	Open
Recall Number	Z-1047-2015
Recall Event ID	70288[23]
Premarket Notification 510(K) Number	K022536[24]
Product Classification	Accessories, Blood Circuit, Hemodialysis[25] - **Product Code** KOC[26]
Product	Fresenius Crit Line in a Clip (CLiC) with SW version 2.51 Model Number: CL10041001. A continuous real-time monitor for non-invasive hematocrit, oxygen saturation and percent change in blood volume calculation during hemodialysis treatment.
Code Information	Serial Numbers: 1C31M140038 1C31M140040 1C31M140041 1C31M140042 1C31M140033 1C31M140034 1C31M140035 1C31M140030 1C31M140075 1C31M140031 1C31M140027 1C31M140054 1C31M140057 1C31M140060 1C31M140039 1C31M140056 1C32M140005, 1C32M140059, 1C32M140058, 1C32M140014, 1C32M140013, 1C32M140004, 1C32M140012, 1C32M140011, 1C32M140009, 1C32M140008, 1C32M140003, 1C32M140007, 1C32M140006, 1C32M140023, 1C32M140021, 1C32M140022, 1C32M140020, 1C31M140073, 1C31M140050
Recalling Firm/ Manufacturer	Fresenius Medical Care Holdings, Inc. 920 Winter St Waltham, Massachusetts 02451-1521
Manufacturer Reason for Recall	Potential for misinterpretation of the graphic display of the Blood Volume (BV) slope
FDA Determined Cause [2]	DESIGN: Device Design
Action	FMCRTG, LLC representatives contacted Clinics on 12/19/14 by visit/telephone phone) and removed all CLiC units.
Quantity in Commerce	35 units
Distribution	CT, NY
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[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 = KOC and Original Applicant = FRESENIUS MEDICAL CARE[29]

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