Class 2 Device Recall Delta

See Related Information[22]

Date Initiated by Firm	March 28, 2017
Create Date	April 10, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1772-2017
Recall Event ID	76862[23]
510(K)Number	K152407[24]
Product Classification	Monitor, physiological, patient(with arrhythmia detection or alarms)[25] - **Product Code** MHX[26]
Product	Delta, Catalog Number: MS18597 in combination with Scio, Scio Four, Scio Four Oxi plus, Scio Four Oxi, Scio Four plus. Product Usage: The devices are intended to be used in the environment where patient care is provided by Healthcare Professionals, i.e. Physicians, Nurses, and Technicians, who will determine when use of the device is indicated, based upon their professional assessment of the patients medical condition. The Infinity Delta Series (Delta/Delta XL/Kappa) monitors are intended to be used on adult, pediatric, and neonatal populations, with the exception of the parameter Cardiac Output, ST Segment Analysis, and arrhythmia which are intended for use in the adult and pediatric populations only; and tcpO2, which for the neonatal population, is to only be used when the patient is not under gas anesthesia. For combination with Scio gas module: Scio gas module samples breathing gases from adults and pediatrics. The gas module continuously measure the content of CO2, N2O, O2 and one of the anesthetic agents, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane in any mixture and communicates real time and derived gas information to the In-finity monitors.
Code Information	VF10.0 software
Recalling Firm/ Manufacturer	Draegar Medical Systems, Inc. 6 Tech Dr Andover MA 01810-2434
For Additional Information Contact	800-437-2437
Manufacturer Reason for Recall	It was reported that a set low O2 alarm does not go off although the measured O2 level is below the alarm limit.
FDA Determined Cause [2]	Under Investigation by firm
Action	On March 28, 2017, US consignees were sent an Urgent Medical Recall letter and Customer Reply and Order card. Delta family monitors running software version 10.0 in facilities that also have at least one Scio module will be downgraded to software version VF9.1 as a temporary solution Free of Charge. Draeger Medical Systems, Inc. is developing a new software version to resolve the issue (VF10.1). Once available, all Delta family monitors that were running software version VF10.0 will be upgraded with VF10.1 Free of