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Class 2 Device Recall Delta

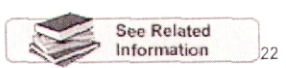


510(k)|DeNovo<sup>6</sup> | Registration & Listing<sup>7</sup> | Adverse Events<sup>10</sup> | Recalls<sup>11</sup>|PMA<sup>12</sup>|HDE<sup>13</sup>|Classification<sup>14</sup>|Standards<sup>15</sup> | CFR Title 21<sup>16</sup>|Radiation-Emitting Products<sup>17</sup>|X-Ray Assembler<sup>18</sup>|Medsun Reports<sup>19</sup>|CLIA<sup>20</sup>|TPLC<sup>21</sup>

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Class 2 Device Recall Delta



<b>Date Initiated by Firm</b>	March 28, 2017
<b>Create Date</b>	April 10, 2017
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-1772-2017
<b>Recall Event ID</b>	<u>76862</u> <sup>23</sup>
<b>510(K)Number</b>	<u>K152407</u> <sup>24</sup>
<b>Product Classification</b>	<u>Monitor, physiological, patient(with arrhythmia detection or alarms)</u> <sup>25</sup> - <b>Product Code</b> <u>MHX</u> <sup>26</sup>
<b>Product</b>	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.
<b>Code Information</b>	VF10.0 software
<b>Recalling Firm/Manufacturer</b>	Draeger Medical Systems, Inc. 6 Tech Dr Andover MA 01810-2434
<b>For Additional Information Contact</b>	800-437-2437
<b>Manufacturer Reason for Recall</b>	It was reported that a set low O2 alarm does not go off although the measured O2 level is below the alarm limit.
<b>FDA Determined Cause<sup>2</sup></b>	Under Investigation by firm
<b>Action</b>	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