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### Class 2 Device Recall Liberty Select Cyclor

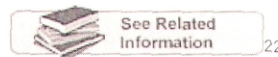


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### Class 2 Device Recall Liberty Select Cyclor



**Date Initiated by Firm**      January 24, 2018

**Create Date**                      April 12, 2018

**Recall Status**<sup>1</sup>                      Open<sup>3</sup>, Classified

**Recall Number**                      Z-1365-2018

**Recall Event ID**                      79625<sup>23</sup>

**510(K)Number**                      K171652<sup>24</sup>

**Product Classification**              System, peritoneal, automatic delivery<sup>25</sup> - Product Code FKX<sup>26</sup>

**Product**                              Liberty Select Cyclor (SW v.2.8.7), Material Number RTL108343

**Product Usage:**  
The device is indicated for acute and chronic peritoneal dialysis.

**Code Information**

0169 LC101663 LC104700 LC105496 LC104300 LC104729 LC016151 LC008705  
 LC105739 LC100202 LC101647, LC024110 LC008000 LC017314 LC021762 LC005315  
 LC023097 LC008399 LC013370 LC021965 LC023691 LC105257 LC012834 LC105189  
 LC015801 LC105242 LC101722, LC105391 LC020828 LC019228 LC020440 LC013265  
 LC016053 LC006340 LC014888 LC009257 LC016530 LC007638 LC000370 LC001068  
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 LC009646 LC004466 LC020700 LC009207 LC100867 LC021431 LC105690 LC006706  
 LC104735 LC014109 LC025018, LC100275 LC003332 LC105605 LC103487 LC103341  
 LC020039 LC014777 LC104351 LC010528 LC013327 LC014965 LC022240 LC023669  
 LC002015 LC011747 LC009635, LC020411 LC105670 LC020158 LC015205 LC103903  
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 LC006763 LC007840 LC106176, LC017833 LC025068 LC103401 LC018126 LC003372  
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LC010308 LC020781 LC012416 LC023693 LC026146 LC020713 LC100474 LC103099  
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 LC020522 LC012486 LC008215, LC020358 LC019780 LC007812 LC012449 LC025800  
 LC011431 LC011478 LC016103 LC102976 LC101801 LC012939 LC010677 LC012992  
 LC009511 LC023800

<b>Recalling Firm/ Manufacturer</b>	Fresenius Medical Care Renal Therapies Group, LLC 920 Winter St Waltham MA 02451-1521
<b>For Additional Information Contact</b>	Fresenius Technical Service 1800-227-2572
<b>Manufacturer Reason for Recall</b>	The recalling firm identified a software issue related to the Patient Line Check (PLC) which may result in an increased risk of <i>Overfill</i> (also known as <i>Increased Intraperitoneal Volume</i> , IIPV). <i>Overfill</i> /IIPV may result in serious injury or death.
<b>FDA Determined Cause <sup>2</sup></b>	Software design
<b>Action</b>	On 01/25/2018, the recalling firm sent Urgent Medical Device Correction letters to affected Home Therapy Nurse Managers (HTNs). On 01/31/2018, the firm sent letters to affected patients. The letters informed customers of the recall and stated that patients who are considered "slow drainers" and experience M65 Scale warnings during one or more drain cycles are at increased risk. On 03/29/2018, the firm sent out a second Urgent Medical Correction Letter to HTNs, followed by a patient communication sent on 04/02/2018. In the second communication, the firm amended that slow drainers can develop <i>Overfill</i> /IIPV even without receiving M65 scale warning. Health care providers and patients using the device were advised to monitor drain rates and address the reasons for slow draining, such as constipation, fibrin deposition, peritonitis, and catheter malposition. Health care providers were advised to continue to review risk factors and symptoms of <i>Overfill</i> /IIPV with PD nursing staff and patients with extended drain times. The firm is not requesting the return of the recalled device at this time. For additional information and alternative treatment options, please contact the FMCRTG Medical Information Line at 1-855-616-2309. Hours of operation are 8:30AM-5:00PM (EST), Monday - Friday. Online requests may be submitted at any time at <a href="http://www.fmca-medinfo.com">www.fmca-medinfo.com</a> .
<b>Quantity in Commerce</b>	9293
<b>Distribution</b>	Nationwide distribution.
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report</a> <sup>27</sup>

<sup>1</sup> A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#)<sup>28</sup>.

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

<sup>3</sup> The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

**510(K) Database** [510\(K\)s with Product Code = FKX and Original Applicant = Fresenius Medical Care Renal](#)