FDA

Class 2 Device Recall Liberty Select Cycler

See Related Information[22]

Date Initiated by Firm	January 24, 2018
Create Date	April 12, 2018
Recall Status[1]	*Open[3], Classified*
Recall Number	Z-1365-2018
Recall Event ID	79625[23]
510(K)Number	K171652[24]
Product Classification	System, peritoneal, automatic delivery[25] - **Product Code** FKX[26]
Product	Liberty Select Cycler (SW v.2.8.7), Material Number RTLR108343 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 LC025096 LC101224 LC007713, LC016022 LC023416 LC023815 LC001562 LC026197 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 LC002783 LC013103 LC016231 LC022267 LC003251 LC016529 LC022580 LC104943 LC023514 LC012542 LC020425, LC017718 LC104919 LC001700 LC020332 LC104100 LC104539 LC021831 LC025541 LC026037 LC020427 LC003888 LC018230 LC105376 LC022040 LC024354 LC009807, LC023195 LC003917 LC018110 LC103367 LC105070 LC020886 LC018985 LC103768 LC102487 LC103761 LC021270 LC020435 LC008629 LC104946 LC022746 LC105863, LC015119 LC002685 LC102126 LC008274 LC009650 LC002525 LC001682 LC104693 LC102657 LC105236 LC021937 LC105737 LC016718 LC004752 LC012854 LC019642, LC102559 LC025979 LC104037 LC009186 LC101017 LC002828 LC015082 LC012860 LC102884 LC015023 LC104790 LC011221 LC016746 LC101934 LC012201 LC106215, LC008771 LC024193 LC004208 LC018225 LC102693 LC102027 LC022244 LC105818 LC104848 LC011760 LC017059 LC105035 LC019777 LC003640 LC104976 LC019899, LC016029 LC105807 LC020697 LC102385 LC105101 LC101171 LC014783 LC005594 LC012473 LC104441 LC100262 LC018312 LC100053 LC013988 LC006417 LC105976, LC025577 LC021376 LC003505 LC015572 LC010768 LC105053 LC025195 LC017309 LC016329 LC101906 LC104461 LC105911 LC100982 LC006763 LC007840 LC106176, LC017833 LC025068 LC103401 LC018126 LC003372 LC101527 LC006568 LC010220 LC024964 LC004743 LC014866 LC105314 LC104176 LC008580 LC001385 LC014882, LC013232 LC101272 LC005638 LC105708 LC004749 LC104177 LC102863 LC024470 LC102054 LC009802 LC101821 LC025060 LC104867 LC005579 LC006270 LC005490, LC013510 LC103928 LC011909 LC015733 LC105353 LC003726 LC004206 LC009558 LC004702 LC024026 LC104250 LC015830 LC002726 LC004051 LC026246 LC002532, LC019175 LC011335 LC016519 LC004866 LC006777 LC105390 LC023377 LC006045 LC014239 LC017895 LC006959 LC018823 LC103032 LC020275 LC104813 LC009786, LC020405 LC026016 LC105650 LC013521 LC007067

	LC010308 LC020781 LC012416 LC023693 LC026146 LC020713 LC100474 LC103099 LC017179 LC100696 LC006667, LC103009 LC102581 LC003525 LC105512 LC104664 LC012392 LC105305 LC006147 LC024957 LC005257 LC104068 LC021471 LC000017 LC103622 LC104010 LC010918, LC002265 LC017988 LC023254 LC024216 LC101988 LC022322 LC101574 LC025290 LC102503 LC018039 LC017962 LC025270 LC000724 LC020017 LC105635 LC023747, LC004590 LC011897 LC015684 LC006341 LC104061 LC007154 LC103552 LC001426 LC102824 LC009503 LC102734 LC010920 LC003075 LC101252 LC006637 LC018226, LC016889 LC025544 LC018822 LC102272 LC103179 LC101436 LC021087 LC018027 LC104883 LC104776 LC015463 LC019159 LC017208 LC100801 LC024895 LC104531, LC019672 LC005180 LC019976 LC104485 LC105056 LC105664 LC104917 LC105199 LC105891 LC100348 LC016623 LC008104 LC024792 LC105853 LC104529 LC100118, LC025775 LC003134 LC025008 LC104713 LC105584 LC020889 LC011548 LC103881 LC001850 LC102620 LC021019 LC010660 LC025261 LC009455 LC105777 LC004252, LC101104 LC103767 LC102696 LC013036 LC022166 LC104378 LC102261 LC006457 LC007330 LC025985 LC024651 LC104320 LC104118 LC105239 LC006287 LC105784, LC104336 LC009898 LC105155 LC018139 LC024410 LC016336 LC100044 LC104318 LC019688 LC005505 LC101136 LC021170 LC000664 LC008547 LC025487 LC003933, LC104789 LC015891 LC105601 LC104801 LC021407 LC103500 LC106003 LC104557 LC024963 LC102536 LC105066 LC103165 LC009341 LC020522 LC012486 LC008215, LC020358 LC019780 LC007812 LC012449 LC025800 LC011431 LC011478 LC016103 LC102976 LC101801 LC012939 LC010677 LC012992 LC009511 LC023800
Recalling Firm/ Manufacturer	Fresenius Medical Care Renal Therapies Group, LLC 920 Winter St Waltham MA 02451-1521
For Additional Information Contact	Fresenius Technical Service 1800-227-2572
Manufacturer Reason for Recall	The recalling firm identified a software issue related to the Patient Line Check (PLC) which may result in an increased risk of Overfill (also known as Increased Intraperitoneal Volume, IIPV). Overfill/IIPV may result in serious injury or death.
FDA Determined Cause [2]	*Software design*
Action	*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 Overfill/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 Overfill/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 www.fmcna-medinfo.com.
Quantity in Commerce	9293
Distribution	Nationwide distribution.
Total Product Life Cycle	*TPLC Device Report*[27]

[1] 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[28].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
[3] 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