Kidney Community Emergency Response

FDA MedWatch

KCER Release Date: July 8, 2019

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REVACLEAR 300 Dialyzer, Product Code 114745L

Date Initiated by Firm	May 31, 2019
Creation Date	July 1, 2019
Recall Status	Ongoing
Recall Number	Z-1908-2019
Recall Event ID	83015
Product Classification	Class II
Product	REVACLEAR 300 Dialyzer, Product Code 114745L indicated for treatment of chronic and acute renal failure by hemodialysis.
Code Information	UDI 07332414123055 Lot Numbers: C419105401 C419105501 C419105601 C419105701 C419105801 C419105901 C419106001 C419106101 C419106201 C419106301 C419106401 C419106501 C419106601 C419106701 C419106801 C419106901 C419107001 C419107101 C419107201 C419107301 C419107401 C419107501 C419107601 C419107701 C419107801 C419107901 C419108001 C419108101 C419108201 C419108301 C419108401 C419108501 C419108601 C419108701 C419108801 C419108901 C419109001 C419109101 C419109201 C419109301 C419109401 C419109501 C419109601 C419109801 C419110001 C419110101 C419110201 C419110301 C419110401 C419110501 C419110601 C419110701 C419110801 C419111001 C419111101 C419111301 C419111501 C419111601 C419111701
Recalling Firm/ Manufacturer	Baxter Healthcare Corporation 1 Baxter Pkwy Deerfield, IL 60015-4625 United States
For Additional Information	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=173325
Manufacturer Reason for Recall	There is a potential presence of ruptured dialyzer fibers which may lead to a blood leak during treatment.
Quantity in Commerce	1,249,272 units
Distribution	US Nationwide Distribution and Internationally to: Canada and Bermuda