Kidney Community Emergency Response

FDA MedWatch

KCER Release Date: July 8, 2019

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REVACLEAR 400 Dialyzer, Product Code 114746L

Date Initiated by Firm	May 31, 2019
Creation Date	July 1, 2019
Recall Status	Ongoing
Recall Number	Z-1909-2019
Recall Event ID	83015
Product Classification	Class II
Product	REVACLEAR 400 Dialyzer, Product Code 114746L indicated for treatment of chronic and acute renal failure by hemodialysis.
Code Information	UDI 07332414124076 Lot Numbers: C419205101 C419205201 C419205301
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=173326
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	65,403 units
Distribution	US Nationwide Distribution and Internationally to: Canada and Bermuda