FDA MedWatch

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KCER Release Date: March 11, 2020
To: KCER Distribution list- including ESRD Network EDs and QIDs

Class II recall of Ten Lots of the Revaclear Capillary Dialyzer, product code 114745L

Product Description:
Revaclear Capillary Dialyzer 300, REF Revaclear 300 Product Code 114745L

Reason for Recall:
There is the potential presence of particular matter in the header caps of ten lots the Revaclear 300 Dialyzer.

Product Quantity:
101976 devices

Recall Number:
Z-1409-2020

Code Information:
UDI 07332414123055, Lot Numbers: C419124901, C419125001, C419125101, C419125201, C419125401, C419125501, C419125601, C419125801, C419126001, C419126401

Classification:
Class II

Event ID:
84339

Voluntary / Mandated:
Voluntary: Firm initiated
Product Type:
Devices

Initial Firm Notification of Consignee or Public:
Letter

Status:
Ongoing

Distribution Pattern:
Nationwide

Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield, IL 60015-4625
United States

Recall Initiation Date:
11/15/2019

Center Classification Date:
2/28/2020