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