

Enforcement Report - Week of August 21, 2024

Class I Biologics Event

Event ID:

94137

Product Type:

Biologics

Status:

Terminated

Date Terminated:

08/15/2024

Recall Initiation Date:

07/12/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

08/15/2024

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Berkeley Biologics LLC
880 Harbour Way S Ste 100
Richmond, CA 94804-3650
United States

Distribution Pattern:

California, Louisiana, Michigan, New York, Oregon, Texas and Virginia

Associated Products

Product Description:

Human tissue allograft consisting of cryopreserved cancellous and cortical bone.

Product Quantity:

43 and 7 units

Reason for Recall:

Berkeley Biologics LLC was notified that two patients who received ViBone Moldable and alloOss Plus Bone Viable Matrix, i.e., Osteo Viable Matrix (OVM) branded products, from a single donor, were diagnosed with Mycobacterium tuberculosis infection post-operatively. The firm is initiating a voluntary recall of all tissue distributed from the impacted donor including OVM products labeled as ViBone Moldable and alloOss Plus.

Recall Number:

B-0309-2024

Code Information:

TDS222820001; TDS222820004; TDS222820006; TDS222820008; TDS222820010; TDS222820040; TDS222820043; TDS222820108;
TDS222820034; TDS222820110; TDS222820011; TDS222820012; TDS222820014; TDS222820016; TDS222820018; TDS222820002;
TDS222820022; TDS222820024; TDS222820026; TDS222820117; TDS222820028; TDS222820032; TDS222820035; TDS222820037;
TDS222820038; TDS222820020; TDS222820003; TDS222820005; TDS222820112; TDS222820041; TDS222820029; TDS222820107;
TDS222820042; TDS222820039; TDS222820009; TDS222820007; TDS222820013; TDS222820015; TDS222820017; TDS222820019;
TDS222820021; TDS222820023; TDS222820033; TDS222820025; TDS222820027; TDS222820030; TDS222820031; TDS222820116;
TDS222820036; TDS222820115;

Class II Biologics Event

Event ID:

95005

Product Type:

Biologics

Status:

Terminated

Date Terminated:

08/09/2024

Recall Initiation Date:

04/22/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

08/09/2024

Initial Firm Notification of Consignee or Public:

Telephone

Recalling Firm:

Versiti Illinois Inc

1200 N Highland Ave
Aurora, IL 60506-1401
United States

Distribution Pattern:

Illinois

Associated Products

<p>Product Description: Apheresis Platelets, Leukocytes Reduced</p> <p>Product Quantity: 1 unit</p> <p>Reason for Recall: Leukoreduced platelet product, for which platelet concentration did not meet specifications, was distributed.</p> <p>Recall Number: B-0396-2024</p> <p>Code Information: W039724452762</p>

Class II Biologics Event

Event ID:

95007

Product Type:

Biologics

Status:

Terminated

Date Terminated:

08/09/2024

Recall Initiation Date:

05/30/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

08/09/2024

Initial Firm Notification of Consignee or Public:

FAX

Recalling Firm:

Vitalant
717 Yosemite St
Denver, CO 80230-6918
United States

Distribution Pattern:

New Hampshire

Associated Products

<p>Product Description: Apheresis Platelets, Leukocytes Reduced</p> <p>Product Quantity: 1 unit</p> <p>Reason for Recall: Apheresis Platelet product, collected in a manner that compromises the sterility of the collection system, was distributed.</p> <p>Recall Number: B-0398-2024</p> <p>Code Information: W03622409217600O</p>
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Class II Biologics Event

Event ID:

95009

Product Type:

Biologics

Status:
Terminated

Date Terminated:
08/09/2024

Recall Initiation Date:
05/29/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/09/2024

Initial Firm Notification of Consignee or Public:
FAX

Recalling Firm:
ImpactLife
5500 Lakeview Pkwy
Davenport, IA 52807-3481
United States

Distribution Pattern:
Texas

Associated Products

<p>Product Description: Pooled Platelets, Leukocytes Reduced, Irradiated</p> <p>Product Quantity: 1 unit</p> <p>Reason for Recall: Leukoreduced Platelets product, stored with a platelet count higher than was acceptable, was distributed.</p> <p>Recall Number: B-0400-2024</p> <p>Code Information: W038324123471</p>
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Class III Biologics Event

Event ID:
95008

Product Type:
Biologics

Status:
Terminated

Date Terminated:
08/09/2024

Recall Initiation Date:
03/21/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/09/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Atlanta Blood Services
5670 Peachtree Dunwoody Rd Ste 1075
Atlanta, GA 30342-4795
United States

Distribution Pattern:
Georgia

Associated Products

<p>Product Description: Platelets, Pathogen Reduced</p> <p>Product Quantity: 1 unit</p> <p>Reason for Recall: Pathogen Reduced Platelets product, labeled with a volume significantly lower than the product's actual volume, was distributed.</p>

Recall Number:

B-0399-2024

Code Information:

W311224000346

Class III Biologics Event

Event ID:

95010

Product Type:

Biologics

Status:

Terminated

Date Terminated:

08/09/2024

Recall Initiation Date:

06/10/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

08/09/2024

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

Blood Connection, Inc. (The)
101 Kitty Hawk Dr
Morrisville, NC 27560-8511
United States

Distribution Pattern:

North Carolina

Associated Products

Product Description:

PF24 Plasma

Product Quantity:

1 unit

Reason for Recall:

Plasma product, which may have reached an unacceptable temperature during shipping, was distributed.

Recall Number:

B-0401-2024

Code Information:

W121624402496