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✓ Facility

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Annual Registration Successful

Facility: Terumo BCT, Inc., Lakewood, Colorado, UNITED STATES

You have successfully updated your registration and listing information for 2025.

Your registration will be valid through Dec 31, 2025.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2025.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 9002708.

Facility Information

Registration Number:

1722028

Initial Importer:

Y

Facility Name:

Terumo BCT, Inc..

Legal Name:

Address:

**10811 W COLLINS AVE,
Lakewood, Colorado, 80215, UNITED STATES**

DUNS Number:

801679200

Foreign Trade Zone:

N

Facility URL:

Other Business Trade Name(s):

Establishment located on a campus:

Owner/Operator Information

Owner/Operator Number:

9002708

Contact Name:

Corrine Lucas

Company:
TERUMO BCT, INC.

Address: **10811 WEST COLLINS AVE., --
Lakewood, COLORADO, 80215, UNITED STATES**

Telephone:
1 - 720 - 6106034

Fax:
303 - 2314756

E-mail: **corraine.lucas@terumobct.com**

DUNS Number:
801679200

Official Correspondent Information

Contact Name:
Corrine Lucas

Company:
TERUMO BCT, INC.

Address: **10811 WEST COLLINS AVE., --
Lakewood, COLORADO, 80215, UNITED STATES**

Telephone:
1 - 720 - 6106034

Fax:
303 - 2314756

E-mail: **corraine.lucas@terumobct.com**

DUNS Number:
801679200

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
D211155	K131744		LKN	Separator, automated, blood cell and plasma, therapeutic	Manufacturer
D301232	BK970005		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D301231	BK150269		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D060837	BK080010		MY Y	Separator, semi-automated, blood component	Manufacturer

D166019	K893962		LKN	Separator, automated, blood cell and plasma, therapeutic	Manufacturer
D300941	BK910020		KZL	DEVICE, WARMING. BLOOD AND PLASMA	Manufacturer
D300940	BK920036		KSR	CONTAINER, EMPTY, FOR COLLECTION & PROCESSING OF BLOOD & BLOOD COMPONENTS	Manufacturer
D300943	BK900003		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D195824	BK070018		KSB	SET, TRANSFER (BLOOD/PLASMA)	Manufacturer
D300942	K900105		LKN	Separator, automated, blood cell and plasma, therapeutic	Manufacturer
D195825	BK860041		KSB	SET, TRANSFER (BLOOD/PLASMA)	Manufacturer Specification Developer
D300945	BK890032		KSB	SET, TRANSFER (BLOOD/PLASMA)	Manufacturer
D195826	BK950039		KSR	CONTAINER, EMPTY, FOR COLLECTION & PROCESSING OF BLOOD & BLOOD COMPONENTS	Repackager/Relabeler
D300944	BK900028		KSB	SET, TRANSFER (BLOOD/PLASMA)	Manufacturer
D300947	BK900002		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300949	BK860012		KSB	SET, TRANSFER (BLOOD/PLASMA)	Manufacturer
D195829	BK110071		KSB	SET, TRANSFER (BLOOD/PLASMA)	Manufacturer
D300948	BK900004		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300939	BK920040		KSS	SUPPLIES, BLOOD-BANK	Manufacturer

D455899	BK170098		KSB	SET, TRANSFER (BLOOD/PLASMA)	Manufacturer
D275258	BK120017		GKT	Separator, automated, blood cell, diagnostic	Specification Developer
D455897	BK180231		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D455898	K172590		LKN	Separator, automated, blood cell and plasma, therapeutic	Manufacturer
D455895	BK180258		MMH	Blood Establishment Computer Software and Accessories	Manufacturer
D455896	K181049		LKN	Separator, automated, blood cell and plasma, therapeutic	Manufacturer
D455893	BK190332		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D455894	K183081		LKN	Separator, automated, blood cell and plasma, therapeutic	Manufacturer
D301230	BK150228		MMH	Blood Establishment Computer Software and Accessories	Manufacturer
D300930	BK960076		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D301227	BK160116		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D301226	BK170059		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D301229	K153601		LKN	Separator, automated, blood cell and plasma, therapeutic	Manufacturer
D301228	BK160108		KSB	SET, TRANSFER (BLOOD/PLASMA)	Manufacturer

D300934	BK950024		KSB	SET, TRANSFER (BLOOD/PLASMA)	Manufacturer
D300936	BK920011		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300935	BK950058		KSS	SUPPLIES, BLOOD-BANK	Manufacturer
D300938	BK930017		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300937	BK940016		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300929	BK980004		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300928	BK990025		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D041535	K071079		LKN	Separator, automated, blood cell and plasma, therapeutic	Manufacturer
D041534	BK950030		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D272612	BK970023		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D272613	BK150321		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D272614	BK110009		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D272615	BK110051		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D272616	BK090003		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D272617	BK010050		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D272618	BK040069		GKT	Separator, automated, blood cell, diagnostic	Manufacturer

D272619	BK110068		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300921	BK030083		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D262245	BK120076		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300920	BK080035		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D262244	BK120012		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D262247	BK130065		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300923	BK010037		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300922	BK030021		MMH	Blood Establishment Computer Software and Accessories	Manufacturer
D262246	BK130031		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D263059	BK140151		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300925	BK020015		MMH	Blood Establishment Computer Software and Accessories	Manufacturer
D262249	BK150251		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D415949	BK170157		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D262248	BK140191		GKT	Separator, automated, blood cell, diagnostic	Manufacturer

D300924	BK010046		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300926	BK010006		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300918	BK080058		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300917	BK080029		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D251083	K151368		LKN	Separator, automated, blood cell and plasma, therapeutic	Manufacturer
D300919	BK080043		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300910	BK120040		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300912	K113480		LKN	Separator, automated, blood cell and plasma, therapeutic	Manufacturer
D300914	K103090		LKN	Separator, automated, blood cell and plasma, therapeutic	Manufacturer
D300916	BK100032		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300906	BK140104		MMH	Blood Establishment Computer Software and Accessories	Manufacturer
D300908	BK130080		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D455900	BK040086		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D475077	BK210635		GKT	Separator, automated, blood cell, diagnostic	Specification Developer

D370733	BK190333		MMH	Blood Establishment Computer Software and Accessories	Manufacturer
D300903	K141938		LKN	Separator, automated, blood cell and plasma, therapeutic	Manufacturer
D300905	BK140158		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300904	BK140180		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D272620	BK870022		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D272621	BK950056		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D041560	BK070001		MMH	Blood Establishment Computer Software and Accessories	Manufacturer
D272622	K831004		LKN	Separator, automated, blood cell and plasma, therapeutic	Manufacturer
D272623	BK950065		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D272624	BK020041		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D272625	K132429		LKN	Separator, automated, blood cell and plasma, therapeutic	Manufacturer
A779327		510(k) exempt	KSD	Device, heat-sealing	Manufacturer
D509556	BK230843		MY Y	Separator, semi-automated, blood component	Manufacturer
D289091	K162365		KCY	TOURNIQUET, PNEUMATIC	Manufacturer

D300960	K760856		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300964	BK070066		MMH	Blood Establishment Computer Software and Accessories	Manufacturer
D203861	BK120049		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D480855	BK210658		KSR	CONTAINER, EMPTY, FOR COLLECTION & PROCESSING OF BLOOD & BLOOD COMPONENTS	Specification Developer
D539222	BK230838		MY Y	Separator, semi- automated, blood component	Complaint File Establishment Specification Developer
D548845	BK241097		GKT	Separator, automated, blood cell, diagnostic	Specification Developer
D300950	K854446		FPA	Set, administration, intravascular	Manufacturer
D538377	BK231035		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300954	BK830003		KSW	SYSTEM, PROCESSING FOR FROZEN BLOOD	Manufacturer
D300953	BK830020		KSR	CONTAINER, EMPTY, FOR COLLECTION & PROCESSING OF BLOOD & BLOOD COMPONENTS	Manufacturer
D300956	BK820001		GKT	Separator, automated, blood cell, diagnostic	Manufacturer
D300958	K790105		GKT	Separator, automated, blood cell, diagnostic	Manufacturer

D300957	K801082		KSR	CONTAINER, EMPTY, FOR COLLECTION & PROCESSING OF BLOOD & BLOOD COMPONENTS	Manufacturer
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Imported Products and Manufacturers

Manufacturer(s) Name	Address	Product Code	Device Name	Premarket Submission Number
KOFU FACTORY OF TERUMO CORP.	1727-1 TSUIJIARAI, SHOWA-CHO, NAKAKOMA-GUN, Yamanashi, 409- 3853, JAPAN	KSB	SET, TRANSFER (BLOOD/PLASMA)	BK970008
KOFU FACTORY OF TERUMO CORP.	1727-1 TSUIJIARAI, SHOWA-CHO, NAKAKOMA-GUN, Yamanashi, 409- 3853, JAPAN	JKA	Tubes, vials, systems, serum separators, blood collection	K983490
Terumo Corporation Fujinomiya Factory	818, MISONODAIRA, FUJINOMIYA-SHI, Shizuoka, 418-0004, JAPAN	KSR	CONTAINER, EMPTY, FOR COLLECTION & PROCESSING OF BLOOD & BLOOD COMPONENTS	BK950039
Terumo Corporation Fujinomiya Factory	818, MISONODAIRA, FUJINOMIYA-SHI, Shizuoka, 418-0004, JAPAN	KSR	CONTAINER, EMPTY, FOR COLLECTION & PROCESSING OF BLOOD & BLOOD COMPONENTS	BK890017
Conroy Medical AB	Hasthagsvagen 14A, UPPLANDS VASBY, Stockholm, SE-194 52, SWEDEN	KSD	Device, heat- sealing	
B Medical Systems SARL	17 op der Hei, Hosingen, Luxembourg, 9809, LUXEMBOURG	JRM	FREEZER	
B Medical Systems SARL	17 op der Hei, Hosingen, Luxembourg, 9809, LUXEMBOURG	KSE	REFRIGERATOR, FREEZER, BLOOD STORAGE	

Date of Initial Registration: 1991-02-07 13:26:27.0