Currently Cleared CBER 510(k)s by Applicant As of 31-OCT-2026

BK980025-0 5D Information Management
Suite 500, 10025 - 102A Avenue
Edmonton, Alberta CANADA T5J 2Z2
Trade Name: Plasma Center Module - 1.0
Cleared Date: 18-MAY-1999
Cleared Under Fifth Dimension Information Systems

BK990022-0 5D Information Management
Suite 500, 10025 - 102A Avenue
Edmonton, Alberta CANADA T5J 2Z2
Trade Name: Donor Management System - 1.0.0
Cleared Date: 10-SEP-1999
Cleared Under Fifth Dimension Information Systems

BK000026-0 5D Information Management
Suite 500, 10025 - 102A Avenue
Edmonton, Alberta CANADA T5J 2Z2
Trade Name: P2K Plasma Center Module 2000 -
1.0
Cleared Date: 22-JUN-2000
Cleared Under Fifth Dimension Information Systems

BK020058-0 5D Information Management
Suite 500, 10025 - 102A Avenue
Edmonton, Alberta CANADA T5J 2Z2
Trade Name: LOGIC - 1.0
Cleared Date: 03-FEB-2003
Cleared Under Fifth Dimension Information Systems

BK040040-0 5D Information Management
Suite 500, 10025 - 102A Avenue
Edmonton, Alberta CANADA T5J 2Z2
Trade Name: LOGIC - 2.0
Cleared Date: 06-OCT-2004
Cleared Under Fifth Dimension Information Systems

BK050060-0 5D Information Management
Suite 500, 10025 - 102A Avenue
Edmonton, Alberta CANADA T5J 2Z2
Trade Name: E-Interview (eQue) - 1.0.0
Cleared Date: 24-MAY-2006
Cleared Under Fifth Dimension Information Systems

BK060051-0 5D Information Management

Suite 500, 10025 - 102A Avenue
Edmonton, Alberta CANADA T5J 2Z2
Trade Name: HaemoConnect (eLynx) - 1.0.0
Cleared Date: 06-MAR-2008

BK070011-0 ABSORBER AB
Drottninggatan 33
Stockholm, SWEDEN SE-103 95
Trade Name: XM-ONE Transplantation Cross Match
Cleared Date: 29-JUL-2008

BK960027-0 ADAC HealthCare Information System
5 Greenway Plaza
Suite 1900
Houston, TX 77046
Trade Name: ADAC Blood Bank System
Cleared Date: 12-AUG-1998

BK180252-0 APEX Biologix
5650 South Green St
Murray, UT 84123
Trade Name: XCELL PRP Platelet Concentrating System 60ml
Cleared Date: 05-APR-2019

BK200512-0 ARC-One Solutions, LLC
7901 Riviera Blvd
Miramar, FL 33023
Trade Name: Regulated Software Application (RSA) - Version 2.0
Cleared Date: 15-OCT-2020

BK870009-0 ARK-Bio-Medical Canada Corp.
#671 Rustico Road
Winsloe, CANADA CIE 1Z2
Trade Name: WesLabs Model 601
Cleared Date: 15-NOV-1989
Cleared Under Rush Enterprises, Inc.

BK130020-0 Abbott Laboratories
Dept 09VA, Bldg AP8-1
100 Abbott Park Road
Abbott Park, IL 60064-3500
Trade Name: ABBOTT PRISM Director
Cleared Date: 14-MAY-2013

BK261345-0 Abbott Laboratories
100 Abbott Park Road
CP01
Abbott Park, IL 60064

Trade Name: HIV Combo Next
Cleared Date: 29-JUN-2026

BK251234-0 Abbott Molecular
1300 E Touhy Ave
Des Plaines, IL 60018
Trade Name: Alinity m HIV-1 AMP Kit
Alinity m HIV-1 Application
Specification File
Alinity m HIV-1 CAL Kit
Alinity m HIV-1 CTRL Kit
Cleared Date: 27-AUG-2025

BK810599-0 Accugenics, Inc.

Costa Mesa, CA 92626
Trade Name: Dade Rh Control Reagent
Cleared Date: 31-MAR-1981

BK820004-0 Accugenics, Inc.

Costa Mesa, CA 92626
Trade Name: Trans-Type Reagents
Cleared Date: 29-OCT-1982

BK830001-0 Accugenics, Inc.

Costa Mesa, CA 92626
Trade Name: Polycation Potentiator System
Cleared Date: 06-MAY-1983

BK860038-0 Accugenics, Inc.

Costa Mesa, CA 92626
Trade Name: Data-Fi Thrombin Reagent
Cleared Date: 16-JAN-1987

BK890018-0 Ackrad Laboratories
70 Jackson Dr.
Cranford, NJ 07016
Trade Name: Ackrad Blood Warming Assembly
Cleared Date: 21-SEP-1990

BK960071-0 AcroMetrix Corporation
6058 Egret Court
Benicia, CA 94510
Trade Name: ViroSure Multi-Marker
Cleared Date: 11-FEB-1998

BK040060-0 AcroMetrix Corporation

6058 Egret Court
Benicia, CA 94510
Trade Name: VeriSure Pro External Quality
Controls
Cleared Date: 03-MAY-2005

BK050061-0 AcroMetrix Corporation
6058 Egret Court
Benicia, CA 94510
Trade Name: VeriSure Pro WNV RNA Negative
External Quality Control
VeriSure Pro WNV RNA Positive
External Quality Control
VeriSure Pro West Nile Virus (WNV)
RNA External Quality Controls:
Cleared Date: 21-DEC-2005

BK060064-0 AcroMetrix Corporation
6058 Egret Court
Benicia, CA 94510
Trade Name: VeriSure Pro HBV DNA External
Quality Control
Cleared Date: 08-FEB-2007

BK960002-0 Activated Cell Therapy Inc.
291 North Bernardo Avenue
Mountain View, CA 94043
Trade Name: ACT Buoyant Density Solution
Cleared Date: 12-AUG-1996

BK190393-0 Aeon Biotherapeutics Corp.
12F., No.58, Ruihu St.
Taipei City, Neihu Dist TAIWAN 11494
Trade Name: Aeon CPKit
Autologous CellPrep Kit
Cleared Date: 05-JUN-2020

BK231016-0 Aeon Biotherapeutics Corp.
12F., No.58, Ruihu St.
Taipei City, Neihu Dist TAIWAN 11494
Trade Name: Aeon ACKit
Cleared Date: 16-FEB-2024

BK150217-0 Alba Bioscience Limited
5 James Hamilton Way
Milton Bridge
Penicuik, Midlothian UNITED KINGDOM EH26 0BF
Trade Name: ALBAsure QC Kit
Cleared Date: 01-APR-2015
Cleared Under ALBA Bioscience Limited (doing business as Quotient)

BK170013-0 Alba Bioscience Limited
21 Ellen's Glen Rd
Edinburgh,
Trade Name: AlbaQ-Chek (R) Simulated Whole Blood Controls, Model Z498
Cleared Date: 09-MAY-2017

BK170086-0 Alba Bioscience Limited
21 Ellen's Glen Rd
Edinburgh,
Trade Name: AlbaQ-Chek Simulated Whole Blood Controls
Cleared Date: 20-OCT-2017

BK180286-0 Alba Bioscience Limited
James Hamilton Way
Penicuik, Midlothian UNITED KINGDOM EH26 0BF
Trade Name: ALBAcyte lgG Sensitized Red Blood Cells II
Cleared Date: 05-FEB-2019

BK190389-0 Alba Bioscience Limited
James Hamilton Way
Penicuik, Midlothian UNITED KINGDOM EH26 0BF
Trade Name: ALBAcheck BGS Monoclonal Control
ALBAcheck BGS Monoclonal Control
Cleared Date: 26-NOV-2019

BK251265-0 Alba Bioscience Limited
5 James Hamilton Way
Milton Bridge
Penicuik, Midlothian UNITED KINGDOM EH26 0BF
Trade Name: ORTHO Elution Kit
ORTHO Elution Kit (6324444)
Cleared Date: 12-NOV-2025

BK251272-0 Alba Bioscience Limited
5 James Hamilton Way
Milton Bridge
Penicuik, Midlothian UNITED KINGDOM EH26 0BF
Trade Name: Alba Elution Kit
Alba Elution Kit (FD313M)
Cleared Date: 14-NOV-2025

BK160045-0 Alliance Partners LLC
14206 Northbrook Drive
San Antonio, TX 78232
Trade Name: Cyclone Platelet Rich Plasma (PRP) Concentrating System

Cleared Date: 04-NOV-2016

BK170108-0 Alliance Partners LLC
14206 Northbrook Drive
San Antonio, TX 78232
Trade Name: Cyclone Blood & Bone Marrow
Concentration (BBMC) System
Cleared Date: 02-JAN-2018

BK190361-0 Alliance Technologies, LLC
1552 West Griswold Rd
Phoenix,, AZ 85021
Trade Name: BloodRelay 1.0.0
Cleared Date: 17-SEP-2019

BK210620-0 Alliance Technologies, LLC
1552 West Griswold Rd
Phoenix,, AZ 85021
Trade Name: BloodRelay - 1.0.0
BloodRelay 1.1.0
Cleared Date: 04-OCT-2021

BK220668-0 Alma Lasers, Inc
485 Half Day Rd
Suite 100
Buffalo Grove, IL 60089
Trade Name: LipoFlow System with VorFat Kit
VorFat System
Cleared Date: 12-JUN-2023

BK220713-0 Alma Lasers, Inc
485 Half Day Rd
Suite 100
Buffalo Grove, IL 60089
Trade Name: Alma LipoFlow System (K171242)
Cleared Date: 14-JUL-2017

BK940054-0 Alpha Scientific Corporation
P.O. Box 725
Southeastern, PA 19399
Trade Name: SEG-Safe (TM)
Cleared Date: 15-MAR-1995

BK950014-0 Alpha Scientific Corporation
P.O. Box 725
Southeastern, PA 19399
Trade Name: SEG-SAFE
Cleared Date: 31-MAR-1995

BK860014-0 Alpha Therapeutic Corporation

5555 Valley Boulevard
Los Angeles, CA 90032
Trade Name: JMS Double Blood Collection Pack
Cleared Date: 04-JUN-1986

BK870004-0 Alpha Therapeutic Corporation
5555 Valley Boulevard
Los Angeles, CA 90032
Trade Name: Plasma Transfer Pack
Cleared Date: 11-MAR-1987

BK950044-0 Alpha Therapeutic Corporation
13111 Temple Avenue
City of Industry, CA 91746
Trade Name: Transfer Device
Cleared Date: 18-OCT-1995

BK950021-0 Alton Dean Medical, Inc.
1547 West 2290 South
Woods Cross, UT 84087
Trade Name: Alton Dean Model FW-437
Cleared Date: 15-MAY-1995

BK960030-0 American Blood Resources Association
PO Box 669
Annapolis, MD 21404
Trade Name: National Donor Deferral Registry
Cleared Date: 20-MAR-1997

BK010012-0 American Blood Resources Association
147 Old Solomons Island Rd.
Annapolis, MD 21401
Trade Name: National Donor Deferral Registry
(NDDR) - 1.0
Cleared Date: 06-SEP-2001

BK960040-0 American Red Cross
Diagnostic Manufacturing Division
2025 E Street NW
Washington, DC 20006
Trade Name: NBCS 1.1
Cleared Date: 28-FEB-1997

BK090021-0 American Red Cross
Diagnostic Manufacturing Division
2025 E Street NW
Washington, DC 20006
Trade Name: Control Cells
Cleared Date: 24-JUN-2009

BK120042-0 American Red Cross
Diagnostic Manufacturing Division
2025 E Street NW
Washington, DC 20006
Trade Name: DailyChek QC Kit
Cleared Date: 06-OCT-2012

BK820016-0 American Red Cross Blood Services
15601 Crabbs Branch Way
Rockville, MD 20855
Trade Name: ARC HLA Extended Trays
ARC HLA Trays
Cleared Date: 01-JUN-1983

BK840015-0 American Red Cross Blood Services
15601 Crabbs Branch Way
Rockville, MD 20855
Trade Name: Bovine Albumin 3%
Cleared Date: 25-OCT-1984

BK880021-0 American Red Cross Blood Services
15601 Crabbs Branch Way
Rockville, MD 20855
Trade Name: Frozen-Dried Bromelein
Cleared Date: 21-DEC-1988

BK020032-0 American Red Cross Blood Services
Quality and Regulatory Affairs
1616 Fort Myer Drive
Arlington, VA 22209
Trade Name: NGTL Automation System (NAS) -
5.2.0
Cleared Date: 20-MAR-2003

BK850010-0 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name: Rh-Hr Control
Cleared Date: 27-DEC-1985

BK850023-0 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name: Amtec CM-Tec Control
Cleared Date: 30-DEC-1985

BK860002-0 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name: Bovine Albumin 22%

Cleared Date: 03-MAR-1986

BK860003-0 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name: Bovine Albumin 30%
Cleared Date: 03-MAR-1986

BK860008-0 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name: Amtec Anti-A1 Lectin
Cleared Date: 16-JUN-1986

BK860009-0 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name: Amtec Anti-N Lectin
Cleared Date: 18-SEP-1987

BK860010-0 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name: Amtec PS
Cleared Date: 16-DEC-1986

BK860020-0 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name: Amtec R-E-S System
Cleared Date: 25-FEB-1987

BK860021-0 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name: Amtec Coombs Control Cells
Cleared Date: 26-AUG-1986

BK860026-0 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name: Amtec Anti-H Lectin
Cleared Date: 27-JAN-1987

BK860036-0 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name: Model Series, Mini & BB
Cleared Date: 24-FEB-1987

BK870020-0 Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name: Amtec Ficin System
Cleared Date: 02-FEB-1988

BK220698-0 Andrew Technologies LLC
3 Haddon Ave
Haddonfield, NJ 08033
Trade Name: HYDRASOLVE LIPOPLASTY SYSTEM
(K130152)
Cleared Date: 18-APR-2013

BK010024-0 Applied Biosystems
850 Lincoln Centre Drive
Foster City, CA 94404
Trade Name: ViroSeq HIV-1 Genotyping System
Cleared Date: 10-DEC-2002

BK030005-0 Applied Biosystems
1401 Harbor Bay Parkway
Alameda, CA 94502
Trade Name: ViroSeq HIV-1 Genotyping System
Cleared Date: 29-JAN-2003

BK010031-0 Applied Science, Inc.
964-B Golden Gate Terrace
Grass Valley, CA 95945
Trade Name: Hemoflow Model 400 with Data
Scanner
Cleared Date: 23-JAN-2002

BK990011-0 Applied Sciences, Inc.
964-B Golden Gate Terrace
Grass Valley, CA 95945
Trade Name: HemoFlow Donor Monitor
Cleared Date: 16-JUL-1999

BK990019-0 Applied Sciences, Inc.
964-B Golden Gate Terrace
Grass Valley, CA 95945
Trade Name: HemoFlow Donor Monitor and Mixer
Cleared Date: 05-OCT-1999

BK020031-0 Arlington Scientific, Inc.
1840 North Technology Dr.
Springville, UT 84663
Trade Name: ASI TPHA Test
Cleared Date: 30-JAN-2003

BK130001-0 Arlington Scientific, Inc.
1840 North Technology Dr.
Springville, UT 84663
Trade Name: ASiManager-AT
Cleared Date: 24-FEB-2014

BK140192-0 Arlington Scientific, Inc.
1840 North Technology Dr.
Springville, UT 84663
Trade Name: ASi Manager-AT
Cleared Date: 19-FEB-2015

BK170114-0 Arlington Scientific, Inc.
1840 North Technology Dr.
Springville, UT 84663
Trade Name: ASI Evolution - 2800-000
Cleared Date: 28-DEC-2017

BK200488-0 Arlington Scientific, Inc.
1840 North Technology Dr.
Springville, UT 84663
Trade Name: ASI Automated RPR test for
Syphilis for use on the ASI
Evolution
ASI Evolution
Cleared Date: 30-SEP-2020

BK200539-0 Arlington Scientific, Inc.
1840 North Technology Dr.
Springville, UT 84663
Trade Name: ASI Automated RPR test for
Syphilis for use on the ASI
Evolution
ASI Evolution
Cleared Date: 02-FEB-2021

BK940022-0 Arrow International, Inc.
P.O.Box 12888 3000 Bernville Road
Reading, PA 19612
Trade Name: Arrow Qwik-1 TM Blood and Fluid
Administration Set
Cleared Date: 14-JUL-1994

BK950036-0 Arrow International, Inc.
P.O.Box 12888 3000 Bernville Road
Reading, PA 19612
Trade Name: Arrow High Flow Fluid Adm. Set
with Blood Filter &
Cleared Date: 02-AUG-1995

BK200540-0 Arteriocyte Medical Systems, Inc
45 South Street, Suite 3
Hopkinton, MA 01748
Trade Name: Precise Cell Concentration System
Cleared Date: 17-MAR-2022

BK251168-0 Arteriocyte Medical Systems, Inc.
45 South St.
Hopkinton, MA 01748
Trade Name: Precise Cell Concentration System
Cleared Date: 03-FEB-2026

BK070069-0 Arthrex, Inc.
1370 Creekside Boulevard
Naples, FL 34108
Trade Name: Arthrex Double Syringe (ACP, Autologous Conditioned Plasma) System
Cleared Date: 12-DEC-2008

BK170144-0 Arthrex, Inc.
1370 Creekside Boulevard
Naples, FL 34108
Trade Name: Arthrex Thrombinator System
Thrombinator System for use with the Arthrex Angel concentrated Platelet Rich Plasma (PRP) System
Cleared Date: 10-MAY-2018

BK180180-0 Arthrex, Inc.
1370 Creekside Boulevard
Naples, FL 34108
Trade Name: Arthrex Angel System Kits
Cleared Date: 05-JUL-2018

BK180299-0 Arthrex, Inc.
1370 Creekside Boulevard
Naples, FL 34108
Trade Name: Arthrex Thrombinator System
Cleared Date: 07-MAR-2019

BK190383-0 Arthrex, Inc.
1370 Creekside Boulevard
Naples, FL 34108
Trade Name: Arthrex Angel System
Cleared Date: 18-SEP-2019

BK190406-0 Arthrex, Inc.
1370 Creekside Boulevard
Naples, FL 34108

Trade Name: Arthrex Double Syringe (ACP)
System
Cleared Date: 06-NOV-2019

BK200442-0 Arthrex, Inc.
1370 Creekside Boulevard
Naples, FL 34108
Trade Name: Arthrex Double Syringe (ACP)
System
Cleared Date: 09-JUL-2020

BK210655-0 Arthrex, Inc.
1370 Creekside Boulevard
Naples, FL 34108
Trade Name: Arthrex Autologous Conditioned
Plasma (ACP) Max System
Cleared Date: 22-SEP-2022

BK241060-0 Arthrex, Inc.
1370 Creekside Boulevard
Naples, FL 34108
Trade Name: Arthrex Thrombinator System
(ABS-10080)
Cleared Date: 24-APR-2024

BK910017-0 Assoc. of Cape Cod
P.O. Box 224
Woods Hole, MA 02543
Trade Name: Control Standard
Endotoxin/Pepyrogeneration Valid.
Cleared Date: 21-OCT-1991

BK940032-0 Augustine Medical, Inc.
10393 West 70 th Street
Eden Prairie, MN 55344
Trade Name: Bair Hugger Patient Warming Device
Cleared Date: 29-SEP-1994

BK130049-0 B.T.I Biotechnology Institute, S.L.
Leonardo DaVinci 14
Parque Tecnologico De Alava
Minano, Alava SPAIN 01510
Trade Name: BTI Biotechnology Institute S.L.
Endoret Kit for Platelet and
Plasma Separator
Cleared Date: 16-JAN-2014

BK150294-0 B.T.I Biotechnology Institute, S.L.
Leonardo DaVinci 14
Parque Tecnologico De Alava

Minano, Alava SPAIN 01510
Trade Name: ENDORET Kit
Cleared Date: 09-DEC-2015

BK251157-0 B.T.I Biotechnology Institute, S.L.
Leonardo DaVinci 14
Parque Tecnologico De Alava
Minano, Alava SPAIN 01510
Trade Name: ENDORET Kit
Cleared Date: 03-OCT-2025

BK930027-0 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name: Accurun 1
Cleared Date: 25-OCT-1994
Cleared Under Boston Biomedica, Inc.

BK970004-0 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name: ACCURUN155
Cleared Date: 23-APR-1999
Cleared Under Boston Biomedica, Inc.

BK990032-0 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name: Accurun 106 HIV-1 Antigen
Cleared Date: 20-JAN-2000
Cleared Under Boston Biomedica, Inc.

BK010038-0 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name: Accurun 1 Multimarker Negative
Control
Cleared Date: 18-DEC-2001
Cleared Under Boston Biomedica, Inc.

BK040006-0 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name: ACCURUN 315 HIV-1 RNA Positive
Control
Cleared Date: 12-OCT-2004
Cleared Under Boston Biomedica, Inc.

BK040016-0 BBI Diagnostics, A SeraCare Company
375 West Street

West Bridgewater, MA 02379
Trade Name: ACCURUN 305 HCV RNA Positive Quality Control
Cleared Date: 17-DEC-2004
Cleared Under Boston Biomedica, Inc.

BK040064-0 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name: ACCURUN 345 HIV-1 RNA, HCV RNA, HBV DNA Positive Quality Control Series 150
Cleared Date: 29-OCT-2004
Cleared Under Boston Biomedica, Inc.

BK040067-0 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name: ACCURUN 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV)
Cleared Date: 19-NOV-2004
Cleared Under Boston Biomedica, Inc.

BK060022-0 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name: ACCURUN 365 West Nile Virus RNA Positive Quality Control
Cleared Date: 12-JUN-2006

BK060030-0 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name: ACCURUN 804 Nucleic Acid Negative Quality Control (HIV, HCV, HBV, WNV)
Cleared Date: 18-AUG-2006

BK100037-0 BBK Technology LLC
2910 E Highland Ave
Phoenix, AZ 85016
Trade Name: RC-AID
Cleared Date: 13-SEP-2010

BK030027-0 BD Biosciences
2350 Qume Drive
San Jose, CA 95131-1807
Trade Name: BD IMAGN Microvolume Fluorimeter and BD IMAGN rWBC Assay Kit
Cleared Date: 10-JUL-2003

BK050062-0 BD Biosciences
2350 Qume Drive
San Jose, CA 95131-1807
Trade Name: BD HLA-B27 kit
Cleared Date: 27-OCT-2005

BK050073-0 BD Biosciences
2350 Qume Drive
San Jose, CA 95131-1807
Trade Name: BD HLA-B27 System
Cleared Date: 16-FEB-2006

BK110037-0 BD Biosciences
2350 Qume Drive
San Jose, CA 95131-1807
Trade Name: BD Stem Cell Enumeration Kit
Cleared Date: 19-OCT-2011

BK150307-0 BD Biosciences
2350 Qume Drive
San Jose, CA 95131-1807
Trade Name: BD FACSVia System with the BD
Leucocount reagent Assay
Cleared Date: 16-SEP-2016

BK970024-0 BECTON DICKINSON VACUTAINER Systems
1 Becton Drive
Franklin Lakes, NJ 07417
Trade Name: Plasma Preparation Tube - PPT
Cleared Date: 10-AUG-1998

BK980011-0 BECTON DICKINSON VACUTAINER Systems
1 Becton Drive
Franklin Lakes, NJ 07417
Trade Name: VACUTAINER Brand PLUS (Plastic)
Blood Collection Tube with EDTA
Anticoagulant
Cleared Date: 07-JUN-1999

BK210625-0 BIO RAD MEDICAL DIAGNOSTICS GMBH
Industriestrasse 1
, Dreieich GERMANY 63303
Trade Name: IH-500
Cleared Date: 28-FEB-2022

BK230971-0 BIO RAD MEDICAL DIAGNOSTICS GMBH
Industriestrasse 1
, Dreieich GERMANY 63303
Trade Name: IH-500

Cleared Date: 09-AUG-2023

BK210593-0 BIQ-Health Solutions, Lda
Rua ferreira de Castro, 20C
Barcarena, Lisbon PORTUGAL 2730-081
Trade Name: BTrac
Cleared Date: 13-AUG-2021

BK820008-0 BMT Incorporated
7315 Hazeltine Boulevard
Excelsior, MN 55331
Trade Name: BMT Model 24 Bloodmixer
Cleared Date: 22-OCT-1982

BK220715-0 BSL Co.
6-13, Chilsan-ro 237beon-gil
, Gimhae-si, Gyeongsangnam-do KOREA, SOUTH 51006
Trade Name: Automatic Tissue Processing Unit
(K172717)
Cleared Date: 25-MAY-2018

BK220722-0 BSL Co.
6-13, Chilsan-ro 237beon-gil
, Gimhae-si, Gyeongsangnam-do KOREA, SOUTH 51006
Trade Name: Smart Kit Basic, Smart Kit Pro
(K202443)
Cleared Date: 11-MAR-2021

BK251248-0 Bahia Medical
7250 Dallas Parkway
Suite 400
Plano, TX 75024
Trade Name: PRiSM PRP, 10 mL (PRP10)
PRiSM PRP, 20 mL (PRP20)
PRiSM PRP, 30 mL (PRP30)
PRiSM PRP, 40 mL (PRP40)
Cleared Date: 23-DEC-2025

BK940031-0 Bard Radiology
10115 Highway 142
Covington, GA 30209
Trade Name: True-Pulse Infusion Catheter
Cleared Date: 27-APR-1995

BK100063-0 Barkey GmbH & Co KG
Gewerbestrasse 8
D-33818 Leopoldshoehe
, Leopoldshoehe GERMANY 33818
Trade Name: plasmatherm
Cleared Date: 14-SEP-2017

BK170028-0 Baxalta US Inc.
One Baxter Way
Westlake Village, CA 91362
Trade Name: myPKFiT for ADVATE Version 2.0
Cleared Date: 14-DEC-2017

BK900010-0 Baxter Healthcare Corporation
1851 Delaware Parkway
Miami, FL 33152
Trade Name: Dade Chemically Modified Control Reagent
Cleared Date: 21-SEP-1990

BK920025-0 Baxter Healthcare Corporation
1 Baxter Pkwy.
Deerfield, IL 60015
Trade Name: Dade Fetal-Cyte Screening Kit
Cleared Date: 05-AUG-1993

BK940062-0 Baxter Healthcare Corporation
1 Baxter Pkwy.
Deerfield, IL 60015
Trade Name: Cryocyte TM
Cleared Date: 27-DEC-1994

BK950049-0 Baxter Healthcare Corporation
9 Parker
Irvine, CA 92618
Trade Name: Cryocyte Freezing Container
Cleared Date: 14-FEB-1996

BK960010-0 Baxter Healthcare Corporation
9 Parker
Irvine, CA 92618
Trade Name: Cell Wash Set
Cleared Date: 22-MAY-1996

BK980001-0 Baxter Healthcare Corporation
1 Baxter Pkwy.
Deerfield, IL 60015
Trade Name: CulturePro Tissue Culture Flask
Cleared Date: 19-FEB-1998

BK980012-0 Baxter Healthcare Corporation
1 Baxter Pkwy.
Deerfield, IL 60015
Trade Name: N/A
Cleared Date: 18-MAY-1998

BK020002-0 Baxter Healthcare Corporation
550 North Brand Blvd.
Glendale, CA 91203
Trade Name: Serology SQL LIMS - 1.0
Cleared Date: 07-AUG-2002

BK020059-0 Baxter Healthcare Corporation
25212 West ILL Route 120
RoundLake, IL 60073
Trade Name: ALYX Component Collection System
Cleared Date: 23-JAN-2003

BK170033-0 Baxter Healthcare Corporation
32650 North Wilson Rd
Round Lake, IL 60073
Trade Name: DUO Set
DUO Set A
DUPLOCATH Application Catheter
DUPLOJECT
Cleared Date: 24-JUL-2017

BK030052-0 Bayer HealthCare Diagnostics Division
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 CANADA
Trade Name: TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 08-OCT-2003

BK040052-0 Bayer HealthCare Diagnostics Division
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 CANADA
Trade Name: TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 15-OCT-2004

BK050035-0 Bayer HealthCare Diagnostics Division
P.O. Box 2466
Berkeley, CA 94702-5828
Trade Name: TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 20-SEP-2005

BK010044-0 Beckman Coulter, Inc.
11800 SW 147 Avenue
(M/C: 31-B06)
Miami, FL 33196-2500
Trade Name: stemONE System for EPICS XL/
XL-MCL Flow Cytometry Systems
Cleared Date: 20-MAY-2002

BK020063-0 Beckman Coulter, Inc.
11800 SW 147 Avenue
(M/C: 31-B06)
Miami, FL 33196-2500
Trade Name: LeukoSure Enumeration Kit with
Leuko-Trol RBC Control Cells and
Leuko Trol Platelet Control Cells
Cleared Date: 03-FEB-2003

BK040032-0 Beckman Coulter, Inc.
11800 SW 147 Avenue
(M/C: 31-B06)
Miami, FL 33196-2500
Trade Name: Stem-Kit Reagents
Cleared Date: 05-MAY-2004

BK040055-0 Beckman Coulter, Inc.
11800 SW 147 Avenue
(M/C: 31-B06)
Miami, FL 33196-2500
Trade Name: stemCXP System for the FC 500 with
CXP Software
Cleared Date: 16-SEP-2004

BK180292-0 Beckman Coulter, Inc.
250 South Kraemer Blvd
Brea, CA 92821
Trade Name: PK7400 Automated Microplate System
Cleared Date: 07-MAY-2020

BK210639-0 Beckman Coulter, Inc.
11800 SW 147 Avenue
(M/C: 31-B06)
Miami, FL 33196-2500
Trade Name: Stem-Kit Reagents, stemCXP System
Cleared Date: 15-DEC-2021

BK230833-0 Beckman Coulter, Inc.
1000 Lake Hazeltine Dr
Chaska, MN 55318
Trade Name: Access HIV Ag/Ab combo
Access HIV Ag/Ab combo Calibrators
Access HIV Ag/Ab combo QC
Cleared Date: 27-JUL-2023

BK230961-0 Beckman Coulter, Inc.
11800 SW 147 Avenue
(M/C: 31-B06)
Miami, FL 33196-2500
Trade Name: AQUIOS CL Flow Cytometer

AQUIOS STEM Kit
Cleared Date: 01-SEP-2023

BK930010-0 Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, CA 95131
Trade Name: HLA-B27 Screening Systems
Cleared Date: 09-SEP-1993

BK940015-0 Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, CA 95131
Trade Name: The HLA-B27 System
Cleared Date: 24-OCT-1994

BK960087-0 Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, CA 95131
Trade Name: ProCount Progenitor Cell
Enumeration Kit
Cleared Date: 04-JUN-1998

BK970038-0 Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, CA 95131
Trade Name: Procount Software
Cleared Date: 04-FEB-1999

BK970046-0 Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, CA 95131
Trade Name: LeucoCOUNT Reagent
Cleared Date: 14-AUG-1998

BK950068-0 Becton, Dickinson & Company
1 Becton Drive
Franklin Lakes, NJ 07417-1885
Trade Name: CMV Scan Card Test
Cleared Date: 22-DEC-1995

BK040030-0 Becton, Dickinson & Company
1 Becton Drive
Franklin Lakes, NJ 07417-1885
Trade Name: BD Vacutainer Plus Plastic Serum
Tubes with Clot Activator
Cleared Date: 05-MAY-2004

BK050036-0 Becton, Dickinson & Company
1 Becton Drive
Franklin Lakes, NJ 07417-1885

Trade Name: BD Vacutainer Plus K2EDTA Tubes
BD Vacutainer Plus Serum Tubes
BD Vacutainer SST Glass Tubes
BD Vacutainer SST II Advance Tubes
BD Vacutainer SST Plus Tubes
Cleared Date: 24-FEB-2006

BK060046-0 Becton, Dickinson & Company
1 Becton Drive
Franklin Lakes, NJ 07417-1885
Trade Name: Bd.id Patient Identification
System for Transfusion Management
- V7.00
Cleared Date: 13-FEB-2007

BK180211-0 Becton, Dickinson & Company
7 Loveton Circle, MC 694
Sparks, MD 21152-0999
Trade Name: BD BACTEC Platelet Aerobic/F
Culture vials
BD BACTEC Platelet Anaerobic/F
Culture Vials
Cleared Date: 08-AUG-2018

BK200530-0 Becton, Dickinson & Company
7 Loveton Circle, MC 694
Sparks, MD 21152-0999
Trade Name: BD BACTEC Platelet Aerobic/F
Culture Vials
BD BACTEC Platelet Anaerobic/F
Culture Vials
Cleared Date: 23-DEC-2020

BK210649-0 Becton, Dickinson & Company
1 Becton Drive
Franklin Lakes, NJ 07417-1885
Trade Name: BD Vacutainer ACD A Blood
Collection Tube
BD Vacutainer ACD B Blood
Collection Tube
Cleared Date: 21-JAN-2022

BK210652-0 Becton, Dickinson & Company
2350 Qume Dr
San Jose, CA 95131
Trade Name: BD Stem Cell Enumeration Kit
Cleared Date: 27-JAN-2022

BK230835-0 Becton, Dickinson & Company
2350 Qume Dr

San Jose, CA 95131
Trade Name: BD FACSLyric Flow Cytometer (662875, 662876, 662877, 662878, 663518)
BD FACSuite Clinical BD Leucocount Assay Module (665732)
BD Leucocount Kit
BD Leucocount Kit (662415)
Cleared Date: 24-JUL-2023

BK230980-0 Becton, Dickinson & Company
7 Loveton Circle, MC 694
Sparks, MD 21152-0999
Trade Name: BD Vacutainer K2 EDTA (K2E)
BD Vacutainer K2EDTA Blood Collection Tubes
BD Vacutainer Plus K2EDTA Blood Collection Tubes
BD Vacutainer Plus K2EDTA Tubes
Cleared Date: 17-APR-2024

BK960001-0 Behring Diagnostics
175 University Avenue
Westwood, MA 02090
Trade Name: OPUS CMV
Cleared Date: 09-OCT-1996

BK850022-0 Bellhouse Medical Products Ltd.
Larkhill House; Abingdon
Oxford, OX 14 1AS,
Trade Name: Platelet Screening Test
Cleared Date: 12-NOV-1985

BK150301-0 Belmont Instrument Corporation
780 Boston Road
Billerica, MA 01821
Trade Name: The Belmont buddy(TM) 2 Blood/Fluid Warmer
Cleared Date: 02-SEP-2015

BK251296-0 Bimini Health Tech
8400 Belleview Drive
Suite 125
Plano, TX 75024
Trade Name: PUREGRAFT SYNC Adipose Filtration System
Cleared Date: 12-FEB-2026

BK140112-0 Bio-Rad Laboratories
6565 185th Ave NE

Clinical Diagnostics Group
Redmond, WA 98052-5039
Trade Name: BioPlex? 2200 System
Cleared Date: 23-JUL-2015

BK251254-0 Bio-Rad Laboratories, Inc.
14620 NE North Woodinville Way
Woodinville, WA 98072
Trade Name: Geenius HIV 1/2 Supplemental Assay
Cleared Date: 26-AUG-2025

BK130070-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: MLB 2 10 x 10 mL
Cleared Date: 27-NOV-2013

BK140106-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-1000
Cleared Date: 20-OCT-2016

BK140107-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-COM
Cleared Date: 20-OCT-2016

BK140138-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-Card Neutral
Cleared Date: 20-OCT-2016

BK140139-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-Card Control
Cleared Date: 20-OCT-2016

BK150327-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: Tango Infinity TM
Cleared Date: 16-DEC-2015

BK170019-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303

Trade Name: IH-1000 (Model# 001100)
Cleared Date: 05-MAY-2017

BK170021-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-Com V5.0
Cleared Date: 05-MAY-2017

BK170064-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-Internal QC
Cleared Date: 18-DEC-2017

BK170065-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-Centtrifuge L
Cleared Date: 18-DEC-2017

BK170066-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-Incubator L
Cleared Date: 18-DEC-2017

BK170071-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-Com V5.0
Cleared Date: 26-SEP-2017

BK170075-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-Basic QC
IH-QC System
Cleared Date: 20-DEC-2017

BK180174-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-Com V5.0
Cleared Date: 01-MAY-2018

BK180175-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: TANGO Infinity

Cleared Date: 01-MAY-2018

BK180225-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-Reader 24
Cleared Date: 28-SEP-2018

BK180226-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-Com V5.0
Cleared Date: 28-SEP-2018

BK180274-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-500 Analyzer
Cleared Date: 21-MAR-2019

BK180275-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-Com - 5.0
Cleared Date: 21-MAR-2019

BK190312-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: TANGO infinity
Cleared Date: 25-APR-2019

BK190388-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: TANGO Infinity
Cleared Date: 13-DEC-2019

BK190424-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-COM V5.2 - 12010236
Cleared Date: 20-DEC-2019

BK200548-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-1000
Cleared Date: 12-JAN-2021

BK220769-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-AbID
Cleared Date: 07-DEC-2022

BK970035-0 BioAccess, Inc.
8400 Cedar Street
Silver Spring, MD 20910
Trade Name: Bioaccess Marrow Collection System
Cleared Date: 23-DEC-1998

BK130050-0 BioArray Solutions, Ltd.
35 Technology Drive
Suite 100
Warren, NJ 07059
Trade Name: BeadCheck HEA Positive Control
Cleared Date: 21-MAY-2014

BK130051-0 BioArray Solutions, Ltd.
35 Technology Drive
Suite 100
Warren, NJ 07059
Trade Name: BioArray Imaging System (AIS) 400C
Cleared Date: 21-MAY-2014

BK150270-0 BioArray Solutions, Ltd.
35 Technology Drive
Suite 100
Warren, NJ 07059
Trade Name: Array Imaging System AS 400D
Cleared Date: 15-JUN-2015

BK000046-0 BioE, Inc.
4280 Centerville Road
St. Paul, MN 55127
Trade Name: FluoroTrol Control Kits
Cleared Date: 02-APR-2001
Cleared Under BioErgonomics, Inc.

BK070067-0 BioE, Inc.
4280 Centerville Road
St. Paul, MN 55127
Trade Name: PrepaCyte(R)-CB Processing System
Cleared Date: 17-DEC-2008

BK150347-0 BioLife Plasma Services L.P. - Baxalta US Inc
440 N. Fairway Drive, 2W - 141
Vernon Hills, IL 60061
Trade Name: Lookback Notification System

(LNS), Version 1.0
Cleared Date: 12-FEB-2016

BK160103-0 BioLife Plasma Services L.P. - Baxalta US Inc
440 N. Fairway Drive, 2W - 141
Vernon Hills, IL 60061
Trade Name: Automated Plasma Dispositioning System (APDS) - Version 2.0
Cleared Date: 15-NOV-2016

BK050029-0 BioLife Plasma Services LP
One Baxter Parkway
Deerfield, IL 60015
Trade Name: Donor Information System (DIS) - 3.1
Cleared Date: 07-JUL-2005

BK060017-0 BioLife Plasma Services LP
One Baxter Parkway
Deerfield, IL 60015
Trade Name: Donor Information System (DIS) - 3.2
Cleared Date: 09-MAY-2006

BK080016-0 BioLife Plasma Services LP
One Baxter Parkway
Deerfield, IL 60015
Trade Name: Donor Information System - v3.3
Cleared Date: 02-JUL-2008

BK090001-0 BioLife Plasma Services LP
One Baxter Parkway
Deerfield, IL 60015
Trade Name: Donor Information System (DIS) - version 4.0
Cleared Date: 18-AUG-2009

BK100021-0 BioLife Plasma Services LP
One Baxter Parkway
Deerfield, IL 60015
Trade Name: Donor Information System (DIS)
Cleared Date: 18-JUN-2010

BK120064-0 BioLife Plasma Services LP
One Baxter Parkway
Deerfield, IL 60015
Trade Name: Donor Information System (DIS) v 6.0
Cleared Date: 19-DEC-2012

BK120069-0 BioLife Plasma Services LP
One Baxter Parkway
Deerfield, IL 60015
Trade Name: Automated Plasma DIspositioning System (APDS) v1.0
Cleared Date: 31-MAY-2013

BK140164-0 BioLife Plasma Services LP
One Baxter Parkway
Deerfield, IL 60015
Trade Name: Donor Information System (DIS) - 7.0
Cleared Date: 20-OCT-2014

BK241136-0 BioLife Plasma Services LP
1200 Lakeside Drive
Bannockburn, IL 60015
Trade Name: Lookback Notification System - 2.0
Cleared Date: 20-FEB-2025

BK251307-0 BioLife Plasma Services LP
1200 Lakeside Drive
Bannockburn, IL 60015
Trade Name: Donor Information System - 9.0
Cleared Date: 11-AUG-2026

BK970017-0 BioMerieux
1022 Hingham Street
Rockland, MA 02370
Trade Name: HLA-DR Oligo Detection Kit
Cleared Date: 28-MAY-1998

BK251216-0 BioMonde
62 Forest Street
Suite 300
Marlborough, MA 01752
Trade Name: FBioMonde Larval Debridemntl Therapy Products - BioBag 50/I100/200/300/400
FBioMonde Larval Debridemntl Therapy Products - BioBag 50/I100/200/300/400 (K131221)
Larval Debridemnt Therapy Products - BioBag 50/I100/200/300/400 (K131221)
Cleared Date: 28-AUG-2013

BK251219-0 BioMonde
62 Forest Street
Suite 300

Marlborough, MA 01752
Trade Name: BIOMONDE LARVAL DEBRIDEMENT THERAPY PRODUCTS, LARVAE 100/200/300 AND BIOBAG 50/100/200/300/400 (K142020) BioMonde Larval Debridement Therapy Products - BioBag 50/100/200/300/400 BioMonde Larval Debridement Therapy Products - BioBag 50/100/200/300/400 (K142020)
Cleared Date: 05-NOV-2014

BK130028-0 Biofortuna LTD
1 Hawkshead Road
Croft Business Park
Wirral
, Merseyside UNITED KINGDOM CH62 3RJ
Trade Name: Biofortuna Ltd. SSPGo HLA Typing Kit
Cleared Date: 19-DEC-2013
Cleared Under Biofortuna LTD

BK261388-0 Biolytical Laboratories Inc
Unit 406 - 13251 Delf Pl
Richmond, British Columbia CANADA V6V2A2
Trade Name: INSTI HIV-1/HIV-2 Antibody Test (90-1019)
Cleared Date: 14-SEP-2026

BK090082-0 Biomat USA, Inc.
1311 Temple Avenue
City of Industry, CA 91746
Trade Name: SGP Version 7.0 (Plasma Management System)
Cleared Date: 01-OCT-2010

BK180240-0 Biomat USA, Inc.
2410 Lillyvale Ave
Los Angeles, CA 90032
Trade Name: GDS (Grifols Donation System) - 1.0
Cleared Date: 05-NOV-2018

BK200517-0 Biomat USA, Inc.
2410 Lillyvale Ave
Los Angeles, CA 90032
Trade Name: GDS (Grifols Donation System)
Cleared Date: 05-NOV-2020

BK020019-0 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name: PCCS Graft Delivery System
Cleared Date: 19-JUN-2002

BK040036-0 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name: GPS II Platelet Concentrate
Separation Kit
Cleared Date: 18-JUN-2004
Cleared Under Biomet,Inc.

BK050016-0 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name: Fibrostik Plasma Concentrator
Cleared Date: 20-JUL-2005
Cleared Under Biomet,Inc.

BK070003-0 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name: GPS II Platelet Concentration
Separation Kit with ACD-A
Plasmax Plasma Concentrator with
GPS Mini Platelet Concentrate
Separation Kit with ACD-A
Cleared Date: 22-FEB-2007
Cleared Under Biomet,Inc.

BK070026-0 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name: GPS III Mini Platelet Concentrate
Separation Kit with ACD-A
GPS III Platelet Concentrate
Separation Kit with ACD-A
GPS III Platelet Concentrate
Separation Kit with ACD-A Double
Kit
Cleared Date: 06-JUN-2007
Cleared Under Biomet,Inc.

BK070036-0 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name: Vortech Concentration System
Cleared Date: 21-NOV-2007

BK080004-0 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name: Clotalyst and GPS III Mini Platelet Concentrate Separation Kit with ACD-A
Clotalyst and GPS III Platelet Concentrate Separation Kit with ACD-A
Cleared Date: 14-SEP-2017

BK090008-0 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name: MarrowStim Concentration System
Cleared Date: 18-DEC-2009

BK090023-0 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name: CoAxial Applicator System
Cleared Date: 07-AUG-2009

BK100027-0 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name: BioCUE Platelet Concentration Kit
Cleared Date: 26-MAY-2010

BK110040-0 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name: Clotalyst Kit with GPS(R)III Separator
Cleared Date: 23-DEC-2011

BK220690-0 Biomet Biologics, Inc.
56 East Bell Drive

PO Box 587
Warsaw, IN 46581-0587
Trade Name: FAT CONCENTRATION SYSTEM (K100114)
Cleared Date: 29-SEP-2010

BK230844-0 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name: nSTRIDE APS PRP Concentration System
nSTRIDE PRP Concentration System
Cleared Date: 09-AUG-2023

BK970015-0 Biometric Imaging, Inc.
1025 Terra Bella Avenue
Mountain View, CA 94043
Trade Name: CEQer RBC Assay
Cleared Date: 18-SEP-1998

BK970016-0 Biometric Imaging, Inc.
1025 Terra Bella Avenue
Mountain View, CA 94043
Trade Name: CEQer PRP Assay
Cleared Date: 18-SEP-1998

BK970018-0 Biometric Imaging, Inc.
1025 Terra Bella Avenue
Mountain View, CA 94043
Trade Name: STELLer CD34 Assay
Cleared Date: 18-AUG-1998

BK251214-0 Biomonde (A Trading name of Zoobiotic Limited)
225 Turnpike Road
Southborough,, MA 01772
Trade Name: BioMonde Larval Debridement Therapy Products-Larvae 100/200/300
BioMonde Larval Debridement Therapy Products-Larvae 100/200/300 (K123449)
Larval Debridement Therapy Products-Larvae 100/200/300 (K123449)
Cleared Date: 05-MAR-2013

BK251217-0 Biopharm (UK) Ltd.
2 Bryngwili Road
Hendy, Carmarthenshire UNITED KINGDOM SA4 OXT
Trade Name: MEDICINAL LEECHES (K132958)

Medicinal Leech
Medicinal Leech (K132958)
Cleared Date: 19-FEB-2014

BK980035-0 Biopool International, Inc.
1230 Wilson Drive
West Chester, PA 19380-4254
Trade Name: SliDe Chek
Cleared Date: 11-JUN-1999

BK090037-0 Biosafe SA
Route du Petit-Eysins
Eysins, Vaud SWITZERLAND 1262
Trade Name: CryoSC Freezing Bag
Cleared Date: 22-MAR-2010

BK110022-0 Biosafe SA
Route du Petit-Eysins
Eysins, Vaud SWITZERLAND 1262
Trade Name: Sepax Cell Separation and single use kits
Cleared Date: 28-OCT-2011

BK140203-0 Biosafe SA
Route du Petit-Eysins
Eysins, Vaud SWITZERLAND 1262
Trade Name: Sepax Cell Separtaton System and SIngle Use Kits
Cleared Date: 13-FEB-2015

BK840028-0 Biotech Research Laboratories, Inc.
1600 East Gude Drive
Rockville, MD 20850
Trade Name: Run Control for HBsAg Assay
Cleared Date: 25-JAN-1985

BK090069-0 Biotechnology Institute, SL.
C/Leonardo Da Vinci 14B, 1B.
01510 Minano (Alava)
Alava, SPAIN 01510
Trade Name: Endoret Kit
Secondary Product Code: FMI, GKT
Cleared Date: 01-FEB-2010

BK060066-0 Biotest AG
Postfach 10 20 40
D-63266 Dreiech, GERMANY
Trade Name: TANGO Automated Blood Bank Analyzer System, Version 3.0 Service Pack 4

Cleared Date: 17-JAN-2007

BK950015-0 Biotest Diagnostics Corporation
66 Ford Road, Suite 131
Denville, NJ 07834
Trade Name: Biotest DRB-SSO Typing Kit
Cleared Date: 09-JUN-1995

BK960061-0 Biotest Diagnostics Corporation
66 Ford Road, Suite 131
Denville, NJ 07834
Trade Name: Biotest DQB-ELPHA
Cleared Date: 04-AUG-1997

BK960086-0 Biotest Diagnostics Corporation
66 Ford Road, Suite 131
Denville, NJ 07834
Trade Name: Biotest High Resolution
Supplementary Kit
Cleared Date: 03-JUL-1997

BK980007-0 Biotest Diagnostics Corporation
66 Ford Road, Suite 131
Denville, NJ 07834
Trade Name: BIOTEST DRB-ELPHA Low Resolution
(Enzyme Linked Probe Hybridization
Assay)
Cleared Date: 26-JAN-1999

BK980033-0 Biotest Diagnostics Corporation
66 Ford Road, Suite 131
Denville, NJ 07834
Trade Name: LYMPHOSCREEN ABC 60
Cleared Date: 15-DEC-1999

BK980044-0 Biotest Diagnostics Corporation
66 Ford Road, Suite 131
Denville, NJ 07834
Trade Name: Lymphoscreen DR 30 x 2
Cleared Date: 15-DEC-1999

BK020004-0 Biotest Diagnostics Corporation
66 Ford Road, Suite 131
Denville, NJ 07834
Trade Name: Biotest HLA SSP Kit
Cleared Date: 07-AUG-2002

BK080012-0 Biotest Medical Diagnostics GmbH
P.O. Box 10 21 50
63267 Dreiech, GERMANY

Trade Name: (1) Seraclone Control ABO+Rh
(2) Coombscell-E
(3) MLB2
Cleared Date: 23-JUL-2008

BK080013-0 Biotest Medical Diagnostics GmbH
P.O. Box 10 21 50
63267 Dreiech, GERMANY
Trade Name: Alsevers Solution (510(k) exempt but part of system)
Solidscreen II Control B
Solidscreen Negative Control
Tango Optimo Automated Blood Bank Analyzer System with version 3.1
Cleared Date: 23-JUL-2008

BK820009-0 Biotest-Serum-Institut GmbH
Flughafenstrasse 4
6000 Frankfurt/Main 73, GERMANY
Trade Name: Anti-HLA Leukocyte Typing Serum
Cleared Date: 20-JAN-1983

BK820011-0 Biotest-Serum-Institut GmbH
Flughafenstrasse 4
6000 Frankfurt/Main 73, GERMANY
Trade Name: Microdroplet Testing Tray (Lymphotype ABC-72 Well)
Cleared Date: 20-JAN-1983

BK830027-0 Biotest-Serum-Institut GmbH
Flughafenstrasse 4
6000 Frankfurt/Main 73, GERMANY
Trade Name: Microtest Testing Tray (HLA-DR Wells)
Cleared Date: 26-APR-1984

BK170150-0 Biowy Corporation
27031 Vista Terrace
Lake Forest, CA 92630
Trade Name: Biowy Freezing Bag FB1000
Biowy Freezing Bag FB250
Biowy Freezing Bag FB50
Biowy Freezing Bag FB500
Cleared Date: 11-MAY-2018

BK251308-0 Biowy Corporation
27031 Vista Terrace
Lake Forest, CA 92630
Trade Name: Biowy Multichamber Freezing Bag (FBmxn)

Cleared Date: 24-JUL-2026

BK261343-0 Biowy Corporation
27031 Vista Terrace
Lake Forest, CA 92630
Trade Name: Biowy Multi-Chamber Freezing Bag Set
Cleared Date: 29-APR-2026

BK890015-0 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name: Blood Screening/Diagnostic Serum Controls
Cleared Date: 17-APR-1992

BK890019-0 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name: Blood Bank Saline
Cleared Date: 18-JUL-1990

BK920008-0 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name: VIROTROL
Cleared Date: 17-SEP-1992

BK920028-0 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name: Virotrol HIV-2
Cleared Date: 03-JUN-1993

BK930016-0 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name: Virotrol I Reagents (CMV)
Cleared Date: 16-NOV-1993

BK930033-0 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name: Virotrol HIV-Ag
Cleared Date: 27-SEP-1995

BK930034-0 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name: Virotrol III

Cleared Date: 27-JUL-1994

BK950011-0 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name: Viroclear
Cleared Date: 28-AUG-1995

BK960085-0 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name: VIROTROL II
Cleared Date: 03-OCT-1997

BK000041-0 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name: Viroclear
Cleared Date: 28-DEC-2000

BK060052-0 Blackhawk BioSystems,Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name: AmpliTrol III
Cleared Date: 07-NOV-2006

BK960044-0 Blood Bank Computer Systems, Inc.
1501 West Valley Highway, North
Suite 101
Auburn, WA 98001
Trade Name: Blood Bank Control System
Cleared Date: 15-OCT-1997

BK040056-0 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
Trade Name: Blood Bank Control System (BBCS) -
5.0
Cleared Date: 22-OCT-2004

BK040087-0 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
Trade Name: BBCS Lab Interface Application
(BBCS Lab) - 5.0L
Cleared Date: 15-FEB-2005

BK050013-0 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502

Trade Name: BBCS Mobile Application - 5.0M
Cleared Date: 01-JUN-2005

BK090081-0 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
Trade Name: BBCS Hospital Interface
Application (BBCSH), H 1.0.0
Cleared Date: 20-JAN-2010

BK120028-0 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
Trade Name: BBCS BloodTrack Interface
Application (BBCSBT), BT1.0.0
Blood Bank Control System - V. 5.0
Cleared Date: 21-JUN-2012

BK140130-0 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
Trade Name: ABO QuickPass, version 1.0.0
Cleared Date: 10-OCT-2014

BK140142-0 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
Trade Name: BBCS Primary Application, version
5.4.3
Cleared Date: 10-OCT-2014

BK140184-0 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
Trade Name: ABO Wheels - 1.0.0
Cleared Date: 30-DEC-2014

BK140198-0 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
Trade Name: ABO QuickPass - 1.0.0
Cleared Date: 04-FEB-2015

BK160011-0 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
Trade Name: ABO Express - Model 2.0.0
Cleared Date: 26-APR-2016

BK220790-0 Blood Bank Computer Systems, Inc.

7206 Vandermark Rd. E
Bonney Lake, WA 98391
Trade Name: Blood Bank Control Systems - 6.0
Cleared Date: 17-FEB-2023

BK940048-0 BloodCare
9000 Harry Hines Blvd.
Dallas, TX 75235
Trade Name: LifeTrak /Lab (a.k.a. Lab*Care) -
V. 2.01
Cleared Date: 01-OCT-1998

BK100051-0 Boekel Scientific, Inc
855 Pennsylvania Blvd.
Feasterville, PA 19053
Trade Name: Boekel Plasma Thawer, Model 301000
Cleared Date: 22-APR-2011

BK940025-0 Boston Scientific, Inc.
1 Boston Scientific Place
Natick, MA 01760-1537
Trade Name: Katzen Thrombolysis Guideware
Cleared Date: 24-JAN-1996

BK231004-0 Buoy Software, LLC
55 Post Rd West
Westport, CT 06880
Trade Name: Blood Product Questionnaire Module
Cleared Date: 16-NOV-2023

BK261333-0 Buoy Software, LLC
811 Barton Springs Rd
Suite 510
Austin, TX 78704
Trade Name: Blood Product Questionnaire Module
- v2.0.0
Cleared Date: 08-JUN-2026

BK890009-0 C-six Diagnostics, Inc.
9653 N. Granville Rd.
Meguon, WI 53092
Trade Name: Frozen Cell Panel Tray (Human)
Cleared Date: 02-AUG-1989

BK890010-0 C-six Diagnostics, Inc.
9653 N. Granville Rd.
Meguon, WI 53092
Trade Name: Leukocyte Typing Serum Trays
(Human)
Cleared Date: 02-AUG-1989

BK890011-0 C-six Diagnostics, Inc.
9653 N. Granville Rd.
Meguon, WI 53092
Trade Name: Leukocyte Typing Serum Trays
(Human)
Cleared Date: 02-AUG-1989

BK251218-0 CAROLINA BIOLOGICAL SUPPLY COMPANY
2700 York Rd
Burlington, NC 27215
Trade Name: Medicinal Leech
Medicinal Leech (K140907)
Cleared Date: 07-AUG-2015

BK960049-0 CIS-US, Inc.
10 de Angelo Drive
Bedford, MA 01730
Trade Name: DoseWriter
Cleared Date: 25-MAR-1998

BK950024-0 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name: COBE Platelet Filtration and
Storage Set
Cleared Date: 29-NOV-1995
Cleared Under COBE BCT

BK950056-0 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name: Cobe Spectra LRD Leukoreduction
(System Versions)
Cleared Date: 31-JAN-1996
Cleared Under COBE BCT

BK950065-0 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name: Cobe Spectrum Apheresis System
(stem cell collection)
Cleared Date: 12-NOV-2002
Cleared Under COBE BCT

BK960076-0 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name: COBE Spectra LRS Turbo System
Cleared Date: 14-JUL-1997

Cleared Under COBE BCT

BK970005-0 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name: Focussed System
Cleared Date: 13-OCT-1998
Cleared Under COBE BCT

BK970023-0 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name: Collection of pRBC Using the Focussed System
Cleared Date: 13-OCT-1998
Cleared Under COBE BCT

BK980004-0 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name: COBE Spectra Apheresis System Anticoagulant Free Flow Restriction
Cleared Date: 09-JUL-1998
Cleared Under COBE BCT

BK990025-0 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name: Cobe Trima
Cleared Date: 07-APR-2000
Cleared Under COBE BCT

BK990040-0 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name: COBE Trima with the r/LS RBC Leukoreduction Filter
Cleared Date: 03-MAR-2000
Cleared Under COBE BCT

BK050033-0 COBE Cardiovascular, Inc.
14401 West 65th Way
Arvada, CO 80004-3599
Trade Name: COBE Angel Whole Blood Separation System
Cleared Date: 22-AUG-2005
Cleared Under COBE BCT

BK060010-0 COBE Cardiovascular, Inc.

14401 West 65th Way
Arvada, CO 80004-3599
Trade Name: COBE Angel Whole Blood Separation System
Cleared Date: 27-FEB-2006

BK130003-0 CPSI
6600 Wall Street
Mobile, AL 36695
Trade Name: Blood Administration - Version 1800
Cleared Date: 30-APR-2014

BK020020-0 CSL Behring AG
Wankdorfstrasse 10
3014 Bern, SWITZERLAND
Trade Name: System for Plasma Identification (SPI) - 1.0
Cleared Date: 30-OCT-2002
Cleared Under ZLB Behring AG

BK050078-0 CSL Behring AG
Wankdorfstrasse 10
3014 Bern, SWITZERLAND
Trade Name: System for Plasma Identification (SPI) - 2.0.0
Cleared Date: 22-DEC-2005

BK110023-0 CSL Behring AG
Wankdorfstrasse 10
3014 Bern, SWITZERLAND
Trade Name: System for Plasma Identification (SPI), version - 3.1.0
Cleared Date: 08-JUN-2011

BK120002-0 CSL Plasma
900 Broken Sound Parkway
Suite 400
Boca Raton, FL 33487
Trade Name: LOGIC version 3.0.0
Cleared Date: 24-APR-2012
Cleared Under Haemonetics Corporation

BK190430-0 CSL Plasma
900 Broken Sound Parkway
Suite 400
Boca Raton, FL 33487
Trade Name: Anti-D Donor Management and Inventory System (ADIMS) - Version 1.7

Cleared Date: 11-MAR-2020

BK210650-0 CSL Plasma
900 Broken Sound Parkway
Suite 400
Boca Raton, FL 33487
Trade Name: LOGIC - 4.0.8
Cleared Date: 25-JAN-2022

BK251252-0 CUPRINA PTE. LTD.
1090 LOWER DELTA ROAD
#06-08
, Singapore SINGAPORE 169201
Trade Name: MEDIFLY Maggots
Cleared Date: 12-JUN-2026

BK090054-0 Calimex USA Corporation
258 Hollister Avenu
Alameda, CA 94501
Trade Name: Picture-ID
Cleared Date: 11-JAN-2010

BK110070-0 Calimex USA Corporation
258 Hollister Avenu
Alameda, CA 94501
Trade Name: eOrders, Version 1 - 1
Cleared Date: 17-FEB-2012

BK120035-0 Calimex USA Corporation
258 Hollister Avenu
Alameda, CA 94501
Trade Name: Picture-ID Version 2.0
Cleared Date: 17-DEC-2012

BK940027-0 Cardiovascular Dynamics, Inc.
15 Hammond Suite 307
Irvine, CA 92718
Trade Name: CVD Bullett Infusion Catheter
Cleared Date: 27-FEB-1995

BK940028-0 Cardiovascular Dynamics, Inc.
15 Hammond Suite 307
Irvine, CA 92718
Trade Name: CVD Bullett Hi-Flo Infusion
Cleared Date: 27-FEB-1995

BK040002-0 Care Fusion, Inc.
1430 Spring Hill Road, Suite 510
McLean, VA 22102
Trade Name: wBlood Care - 1.0

Cleared Date: 10-NOV-2004

BK080035-0 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name: COBE Spectra Apheresis System
Trima Accel Automated Blood
Component Collection System
Cleared Date: 29-AUG-2008

BK080043-0 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name: Atreus Whole Blood Processing
System
Cleared Date: 29-SEP-2008

BK080058-0 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name: Trima Accel Automated Blood
Component Collection System
Cleared Date: 25-NOV-2008

BK090003-0 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name: Trima Accel System
Cleared Date: 16-FEB-2010

BK100032-0 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name: Trima Accel System Version 6.0
Cleared Date: 06-AUG-2010

BK110009-0 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name: Trima Accel Automated Blood
Component Collection System
Cleared Date: 19-APR-2011

BK110051-0 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name: Trima Accel Automated Blood
Component Collection System
version 5.1.8
Cleared Date: 20-DEC-2011

BK110068-0 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name: Trima Accel Automated Blood COmponent Collection System
Cleared Date: 23-MAR-2012

BK990015-0 Carter BloodCare
2205 Highway 121
Bedford, TX 76021
Trade Name: LifeTrak/Distribution - 2.03
Cleared Date: 22-OCT-1999

BK990027-0 Carter BloodCare
2205 Highway 121
Bedford, TX 76021
Trade Name: LifeTrak/Donor - 2.03
Cleared Date: 15-DEC-1999

BK180246-0 Carter BloodCare
2205 Highway 121
Bedford, TX 76021
Trade Name: Blood Bank Information System - v2.06.00
Cleared Date: 01-NOV-2018

BK200491-0 Carter BloodCare
2205 Highway 121
Bedford, TX 76021
Trade Name: iWeBB electronic Laboratory Information System (iWeBB-eLIS)
Cleared Date: 29-JUL-2020

BK241069-0 Carter BloodCare
2205 Highway 121
Bedford, TX 76021
Trade Name: Blood Bank Information Management System (BBIMS) - 3.01
Blood Bank Information System (BBIMS) - 3.01
Cleared Date: 09-JUL-2024

BK200514-0 Cartiva, Inc.
6120 Windward Pkwy
Alpharetta, GA 30005
Trade Name: Cartiva SCI Disposable Instrumentation set
Cleared Date: 14-AUG-2020

BK020051-0 Cascade Medical Enterprises, LLC
20 Greenup Court
Wayne, NJ 07470
Trade Name: Cascade Medical Fibrinet,
Autologous Platelet System
Cleared Date: 20-DEC-2002

BK030024-0 Cascade Medical Enterprises, LLC
20 Greenup Court
Wayne, NJ 07470
Trade Name: Cascade Medical Fibrinet System
Cleared Date: 02-JUN-2003

BK060006-0 Cascade Medical Enterprises, LLC
20 Greenup Court
Wayne, NJ 07470
Trade Name: Cascade Medical FIBRINET System
Cleared Date: 16-FEB-2006

BK120009-0 Cascade Medical Enterprises, LLC
20 Greenup Court
Wayne, NJ 07470
Trade Name: FIBRINET (R) Autologous PRP System
Cleared Date: 01-AUG-2012

BK170096-0 Cascade Medical Enterprises, LLC
20 Greenup Court
Wayne, NJ 07470
Trade Name: Fibrinet? Platelet System
Fibrinet Platelet System
Cleared Date: 21-NOV-2017

BK030033-0 Celera Corporation
1401 Harbor Bay Parkway
Alameda, CA 94502
Trade Name: ViroSeq HIV-1 Genotyping System
Cleared Date: 11-JUN-2003
Cleared Under Celera Diagnostics, LLC

BK030088-0 Celera Corporation
1401 Harbor Bay Parkway
Alameda, CA 94502
Trade Name: ViroSeq HIV-1 Genotyping System
v2.0
Cleared Date: 22-JAN-2004
Cleared Under Celera Diagnostics, LLC

BK060049-0 Celera Corporation
1401 Harbor Bay Parkway
Alameda, CA 94502

Trade Name: ViroSeq HIV-1 Genotyping System
Cleared Date: 31-AUG-2006
Cleared Under Celera Diagnostics, LLC

BK080026-0 Celera Corporation
1401 Harbor Bay Parkway
Alameda, CA 94502
Trade Name: ViroSeq HIV-1 Genotyping System
v2.0
Cleared Date: 10-JUL-2008
Cleared Under Celera Diagnostics, LLC

BK130039-0 Celera Corporation
1401 Harbor Bay Parkway
Alameda, CA 94502
Trade Name: ViroSeq HIV-1 Genotyping System
v2.0
Cleared Date: 05-SEP-2013

BK150221-0 Celling Biosciences, Inc.
93 Red River St.
Austin, TX 78701
Trade Name: Circle Biologics Autologous
Platelet Separator (APS) System
Cleared Date: 09-JUN-2015

BK130079-0 Cellmedix Holdings, LLC.
19 Park Drive
Franklin, NJ 07416
Trade Name: Centrepid Platelet Concentrator
Cleared Date: 31-JUL-2014

BK880002-0 Cellular Products
688 Main Street
Buffalo, NY 14202
Trade Name: Blood Bank Refrigerator
Cleared Date: 04-MAY-1988

BK950010-0 Centocor, Inc.
200 Great Valley Parkway
Malvern, PA 19355
Trade Name: CAPTIA CMV-TA EIA
Cleared Date: 22-MAR-1995

BK950051-0 Cerner Corporation
2800 Rock Creek Parkway
Kansas City, MO 64117-2551
Trade Name: Pathnet Blood Center (L-2510)
Cleared Date: 16-JUL-1997

BK950053-0 Cerner Corporation
2800 Rock Creek Parkway
Kansas City, MO 64117-2551
Trade Name: Pathnet Blood Bank Transfusion (L-2300)
Cleared Date: 16-JUL-1997

BK950055-0 Cerner Corporation
2800 Rock Creek Parkway
Kansas City, MO 64117-2551
Trade Name: Pathnet Blood Bank Donor (L2400)
Cleared Date: 16-JUL-1997

BK960024-0 Cerner Corporation
2800 Rock Creek Parkway
Kansas City, MO 64117-2551
Trade Name: PathNet Worksystem Blood Bank Transfusion (L2812)
Cleared Date: 16-JUL-1997

BK990007-0 Cerner Corporation
2800 Rock Creek Parkway
Kansas City, MO 64117-2551
Trade Name: HNA Millennium PathNet Blood Bank Transfusion
Cleared Date: 02-NOV-1999

BK030028-0 Cerner Corporation
2800 Rock Creek Parkway
Kansas City, MO 64117-2551
Trade Name: Cerner Millennium PathNet Blood Bank Donor (PA-22200) - 2003.01
Cleared Date: 19-AUG-2003

BK060037-0 Cerner Corporation
2800 Rock Creek Parkway
Kansas City, MO 64117-2551
Trade Name: Cerner Bridge Medical Transfusion Administration and Specimen Collections - 3.3
Cleared Date: 24-MAY-2007

BK860025-0 Cetus Corporation
1400 53rd Street
Emeryville, CA 94608
Trade Name: Pro Group System
Cleared Date: 27-APR-1987

BK050021-0 Charter Medical, Ltd.
3948-A Westpoint Blvd.

Winston-Salem, NC 27103
Trade Name: Charter Medical Transfer Set
Cleared Date: 22-JUL-2005

BK060042-0 Charter Medical, Ltd.
3948-A Westpoint Blvd.
Winston-Salem, NC 27103
Trade Name: Cell Freeze Liquid Nitrogen
Freezing Container
Cleared Date: 03-OCT-2008

BK100049-0 Charter Medical, Ltd.
3948-A Westpoint Blvd.
Winston-Salem, NC 27103
Trade Name: Cell-Freeze Cryogenic Storage
Container
Cleared Date: 07-DEC-2010

BK170004-0 Charter Medical, Ltd.
3948-A Westpoint Blvd.
Winston-Salem, NC 27103
Trade Name: Charter Medical Cell Therapy Fluid
Transfer Set
Cleared Date: 06-OCT-2017

BK910003-0 CharterMed, Inc.
3948-A West Point Blvd.
Winston-Salem, NC 27103
Trade Name: CharterMed Blood Freezing Bag
Cleared Date: 11-MAR-1993

BK960043-0 CharterMed, Inc.
3948-A West Point Blvd.
Winston-Salem, NC 27103
Trade Name: Charter Med Transfer Bags
Cleared Date: 11-SEP-1996

BK000049-0 Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916
Trade Name: Chiron CPT Pooling Software,
Version 2.0.0.2
Cleared Date: 04-DEC-2001

BK010025-0 Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916
Trade Name: Chiron Procleix NAT Tracker - 1.0E
Cleared Date: 03-JAN-2002
Cleared Under Rubin & Poor

BK030030-0 Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916
Trade Name: Procleix NAT Tracker
Cleared Date: 23-MAY-2003
Cleared Under Rubin & Poor

BK040058-0 Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916
Trade Name: Chiron CPT Pooling Software,
Version 2.0.0.2
Cleared Date: 28-JUL-2004

BK040072-0 Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916
Trade Name: Procleix NAT Tracker Software
Version 2.1
Cleared Date: 04-NOV-2004

BK050004-0 Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916
Trade Name: Procleix Optiva RAS
Cleared Date: 08-APR-2005

BK060005-0 Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916
Trade Name: Chiron Procleix NAT Tracker - 3.0
Cleared Date: 01-MAR-2006

BK070007-0 Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916
Trade Name: PROCLEIX NAT TRACKER
Cleared Date: 06-MAR-2007

BK980043-0 Chrono-Log Corporation
2 West Park Road
Havertown, PA 19083-4691
Trade Name: Chrono-log Lumi-Agrregometer
Cleared Date: 22-DEC-1998

BK100014-0 Circle Biologics, Inc.
3650 Annapolis Lane, Suite 105
Minneapolis, MN 55447
Trade Name: Autologous Fluid Concentrator

(AFC) System
Changed with 6/25/10 Submission
to: "Autologous Platelet
Concentrator (APC)(TM) System
Cleared Date: 09-JUL-2010
Cleared Under Circle Biologic, LLC

BK840008-0 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name: IBM 2991 - Change of Ownership
Cleared Date: 08-JUN-1984

BK840009-0 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name: IBM 2997 - Change of Ownership
Cleared Date: 08-JUN-1984

BK870022-0 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name: COBE Spectra Blood Component
Separator
Cleared Date: 20-JUN-1988

BK900002-0 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name: COBE Spectra: Simultaneous
Collection of Platlets and Plasma
Cleared Date: 21-JUN-1990

BK900003-0 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name: COBE Spectra: Change in
Anticoagulant Ratio
Cleared Date: 14-NOV-1990

BK900004-0 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name: COBE Spectra: Single Needle
System
Cleared Date: 21-JUN-1990

BK910020-0 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215

Trade Name: COBE SPECTRATHERM
Cleared Date: 02-NOV-1992

BK920011-0 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name: Cobe Spectra with PCM
Cleared Date: 15-MAY-1995

BK920036-0 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name: COBE Spectra Single-Needle
Extended Life Platelet (ELP) Set
Cleared Date: 06-APR-1993

BK930017-0 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name: COBE Spectra Apheresis System
(Triple Platelet)
Cleared Date: 27-JUL-1994

BK940016-0 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name: COBE Spectra Version 4
Cleared Date: 20-SEP-1994

BK950030-0 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name: COBE Spectra Extended Life
Platelet Set
Cleared Date: 15-FEB-1996

BK970007-0 Community Bio-Resources, Inc.
2197 Parkway Lake Drive
Hoover, AL 35244
Trade Name: Donor Information System - 1.0
Cleared Date: 09-APR-1997

BK960060-0 Community Blood Center of Greater Kansas City
4040 Main Street
Kansas City, MO 64111
Trade Name: CBC Blood System, Version 1.2
Cleared Date: 20-NOV-1997

BK110048-0 Community Blood Centers of South Florida
1700 North State Road 7

Lauderhill, FL 33313
Trade Name: Regulated Software Application (RSA) - 1.0
Cleared Date: 12-JAN-2012

BK920006-0 Connaught Laboratories Limited
Discovery Drive
Swiftwater, PA 18370
Trade Name: CONTINENTAL REFRIG. BLD.BNK. MODEL C-BBRA-1S
Cleared Date: 17-JUL-1992

BK970010-0 Controlled Chemicals, Inc.
317 S. Division
Suite 9
Ann Arbor, MI 48104
Trade Name: CryoGuard Thermal Exposure Indicator
Cleared Date: 26-AUG-1997

BK940026-0 Cook, Inc.
925 S. Curry Pike
Bloomington, IN 47402
Trade Name: Roubin Infusion Catheter
Cleared Date: 29-JUN-1995

BK830008-0 Cooper Biomedical
1230 Wilson Drive
West Chester, PA 19380
Trade Name: W.A.R.M.
Cleared Date: 21-JUN-1983

BK850008-0 Cooper Biomedical
1 Technology Court
Malvern, PA 29355
Trade Name: H.P.C.
Cleared Date: 09-JAN-1986

BK820007-0 Cry-O-Safe, Inc.
999 Airport Road
Lakewood, NJ 08701
Trade Name: Plasma Safe
Cleared Date: 26-JUL-1982

BK190356-0 Cryo-Cell International, Inc.
700 Brooker Creek Blvd
Oldsmar, FL 34677
Trade Name: PrepaCyte -CB Processing System - PCB 2100-270
Cleared Date: 17-JUN-2020

BK820018-0 Cryosan Inc.
            850 Providence Highway
            Dedham, MA 02026
         Trade Name: Dideco BT Series
         Cleared Date: 16-DEC-1982

BK820021-0 Cryosan Inc.
            850 Providence Highway
            Dedham, MA 02026
         Trade Name: Dideco BT790/A
                     Dideco BT792
         Cleared Date: 03-JAN-1983

BK830015-0 Cryosan Inc.
            850 Providence Highway
            Dedham, MA 02026
         Trade Name: Dideco BT 125
                     Dideco BT 225
                     Dideco BT 375
                     Dideco BT 691
         Cleared Date: 31-OCT-1983

BK830016-0 Cryosan Inc.
            850 Providence Highway
            Dedham, MA 02026
         Trade Name: Dideco Progress BT 790/A
         Cleared Date: 07-FEB-1984

BK840011-0 Cryosan Inc.
            850 Providence Highway
            Dedham, MA 02026
         Trade Name: BT 765 Blood Cell Separator
                     Equipment
         Cleared Date: 10-APR-1985

BK840012-0 Cryosan Inc.
            850 Providence Highway
            Dedham, MA 02026
         Trade Name: BT 765 Elutriation Pump
         Cleared Date: 06-FEB-1985

BK870003-0 Cryosan Inc.
            850 Providence Highway
            Dedham, MA 02026
         Trade Name: Cryo-PakTM System
         Cleared Date: 17-APR-1987

BK960012-0 CytoTherm LP
            110 Sewell Avenue

Trenton, NJ 08610
Trade Name: Cyto Therm (T-S)
Cleared Date: 15-APR-1996
Cleared Under Photo-Therm

BK980042-0 CytoTherm LP
110 Sewell Avenue
Trenton, NJ 08610
Trade Name: CytoTherm J
Cleared Date: 07-JAN-1999
Cleared Under Photo-Therm

BK060027-0 CytoTherm LP
110 Sewell Avenue
Trenton, NJ 08610
Trade Name: CytoTherm Plasma Thawing System
Cleared Date: 01-AUG-2006

BK060063-0 CytoTherm LP
110 Sewell Avenue
Trenton, NJ 08610
Trade Name: CytoTherm Cryoprecipitate Thawer,
Model CT-4T.6C
Cleared Date: 04-MAY-2007

BK080019-0 CytoTherm LP
110 Sewell Avenue
Trenton, NJ 08610
Trade Name: CytoTherm Plasma Thawing System
Cleared Date: 16-JUL-2008

BK060007-0 Cytomedix, Inc
416 Hungerford Drive
Rockville, MD 20850
Trade Name: Autologel System
Cleared Date: 20-SEP-2007

BK110046-0 Cytomedix, Inc
416 Hungerford Drive
Rockville, MD 20850
Trade Name: Angel(R) Whole Blood Separation
System
Cleared Date: 07-NOV-2012

BK130060-0 Cytonics Corporation
555 Heritage Drive, Suite 115
Jupiter, FL 33458
Trade Name: Autologous Platelet Integrated
Concentration ("APIC") System
Cleared Date: 17-JAN-2014

BK220684-0 Cytori Therapeutics Inc.
3020 Callan Road
San Diego, CA 92121
Trade Name: CYTORI AFT SYSTEM
CYTORI AFT SYSTEM (K072587)
Cleared Date: 10-DEC-2007

BK220689-0 Cytori Therapeutics Inc.
3020 Callan Road
San Diego, CA 92121
Trade Name: CYTORI PUREGRAFT 250/PURE SYSTEM
(K092923)
FAT CONCENTRATION SYSTEM (K100114)
Cleared Date: 06-JAN-2010

BK220693-0 Cytori Therapeutics Inc.
3020 Callan Road
San Diego, CA 92121
Trade Name: PUREGRAFT 850/PURE SYSTEM
(K113255)
Cleared Date: 07-MAR-2012

BK220699-0 Cytori Therapeutics Inc.
3020 Callan Road
San Diego, CA 92121
Trade Name: PUREGRAFT 50 SYSTEM (K132815)
Cleared Date: 24-JAN-2014

BK950060-0 Cytosol Laboratories, Inc.
55 Messina Drive
Braintree, MA 02184-6783
Trade Name: Y-Type Rejuvenation Set PN7212
Cleared Date: 25-NOV-1996

BK000022-0 DENCO, INC.
P.O.BOX 9600
Wilmington, DE 19809
Trade Name: Total Containment Device
Cleared Date: 18-APR-2000

BK990041-0 DENCO, INC.
P.O.BOX 9600
Wilmington, DE 19809
Trade Name: Total Containment Device
Cleared Date: 21-DEC-1999

BK160084-0 DIAGAST
Parc Eurasant
251, Avenue Eug ne Avin e

BP 9
LOOS Cedex, FRANCE 59374
Trade Name: Neg Control
Cleared Date: 02-FEB-2018

BK190313-0 DIAGAST
Parc Eurasant
251, Avenue Eug ne Avin e
BP 9
LOOS Cedex, FRANCE 59374
Trade Name: PK SYSTEM CONTROL
Cleared Date: 07-MAY-2020

BK130053-0 DSM BIOMEDICAL
735 Pennsylvania Drive
Exton, PA 19341
Trade Name: DSM Biomedical PRP Device
Cleared Date: 25-MAR-2014

BK140176-0 DSM BIOMEDICAL
735 Pennsylvania Drive
Exton, PA 19341
Trade Name: The JEN Device
Cleared Date: 06-MAR-2015

BK950019-0 DUPACO
2620 TEMPLE HEIGHTS DR.
OCEANSIDE, CA 92056
Trade Name: DUPACO BLOOD/FLUID WARMING SET
D25416
Cleared Date: 27-APR-1995

BK950038-0 DUPACO
2620 TEMPLE HEIGHTS DR.
OCEANSIDE, CA 92056
Trade Name: Dupaco Counterflo 300 Blood/Fluid
Warmer
Cleared Date: 01-SEP-1995

BK020057-0 Data Innovations LLC
120 Kimball Ave., Suite 100
South Burlington, VT 05430
Trade Name: imExpress - 7.2.5
Cleared Date: 29-JUL-2003
Cleared Under Data Innovations

BK060053-0 Data Innovations LLC
120 Kimball Ave., Suite 100
South Burlington, VT 05430
Trade Name: Instrument Manager - 8.05.01.10

Cleared Date: 05-JAN-2007
Cleared Under Data Innovations Inc.

BK080052-0 Data Innovations LLC
120 Kimball Ave., Suite 100
South Burlington, VT 05430
Trade Name: INSTRUMENT MANAGER - V 8.07
Cleared Date: 28-OCT-2008
Cleared Under Data Innovations Inc.

BK100046-0 Data Innovations LLC
120 Kimball Ave., Suite 100
South Burlington, VT 05430
Trade Name: Instrument Manager - 8.10.01
Cleared Date: 12-AUG-2010
Cleared Under Data Innovations Inc.

BK120051-0 Data Innovations LLC
120 Kimball Ave., Suite 100
South Burlington, VT 05430
Trade Name: Instrument Manager v8.12
Cleared Date: 17-OCT-2012
Cleared Under Data Innovations Inc.

BK180245-0 Data Innovations LLC
120 Kimball Ave., Suite 100
South Burlington, VT 05430
Trade Name: Instrument Manager - 8.16.10
Cleared Date: 08-NOV-2018

BK070035-0 Defense Blood Standard System
5205 Leesburg Pike
Suite 1000
Falls Church, VA 22041
Trade Name: Defense Blood Standard System
(DBSS) - 10.0.0
Cleared Date: 22-MAY-2008

BK180229-0 Delcon S.r.l.
Via Zanica
Grassobbio, BG ITALY 24050
Trade Name: HEMOMIX 3
HemoMix 3 with DCSX Software
Cleared Date: 04-OCT-2018

BK190429-0 Delcon S.r.l.
Via Zanica
Grassobbio, BG ITALY 24050
Trade Name: HemoMix 4 (Basic version)
HemoMix 4 (Internal optional RFID

installed version)
Cleared Date: 30-JAN-2020

BK231039-0 Delcon S.r.l.
Via Zanica
Grassobbio, BG ITALY 24050
Trade Name: Giotto Monza (BCS03)
Macopress Smart Smarter
Cleared Date: 26-MAR-2025

BK970021-0 Department of Veterans Affairs
P.O. Box 5000
VA Hines Medical Center
Hines, IL 60141
Trade Name: Vista Blood Bank Software (V5.2)
Cleared Date: 23-APR-1999

BK060043-0 Department of Veterans Affairs
P.O. Box 7008
Hines, IL 60141-7008
Trade Name: VistA Blood Establishment Computer
Software (VBECS) - 1.0
Cleared Date: 19-OCT-2006

BK140172-0 Department of Veterans Affairs
P.O. Box 7008
Hines, IL 60141-7008
Trade Name: VistA Blood Establishment Computer
Software (VBECS) - 2.0.0
Cleared Date: 20-NOV-2014

BK180227-0 Department of Veterans Affairs
P.O Box 7008
5th Ave and Roosevelt Rd
Bldg 37
Hines, IL 60141
Trade Name: VistA Blood Establishment Computer
Software (VBECS)
Cleared Date: 01-OCT-2018

BK830025-0 Dia Tech
2525 Shader Road
Orlando, FL 328
Trade Name: DiaCent 2 Automated Cell
Washer/Centrifuge
Cleared Date: 10-JAN-1984

BK840001-0 Dia Tech
2525 Shader Road
Orlando, FL 328

Trade Name: DIACENT 1, Automated Cell
Washer/Centrifuge
Cleared Date: 19-MAR-1984

BK870007-0 DiaClin Laboratories, Inc.
450 10th Circle North
Nashville, TN 37203
Trade Name: SEOPF ROP Tray
Cleared Date: 04-APR-1990

BK241116-0 DiaSorin Inc.
1951 Northwestern Avenue
Stillwater, MN 55082
Trade Name: LIAISON MUREX Control HIV Ab-Ag
HT (318291)
LIAISON MUREX HIV Ab/Ag HT
(318290)
Cleared Date: 10-JUN-2025

BK261335-0 DiaSorin Inc.
1951 Northwestern Avenue
Stillwater, MN 55082
Trade Name: LIAISON MUREX HIV Ab/Ag HT
LIAISON XL
LIAISON diluteX
Cleared Date: 29-MAY-2026

BK120043-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: DG Gel 8 Neutral Gel
Cleared Date: 19-JUL-2013

BK120044-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: Grifols Diluent
Cleared Date: 19-JUL-2013

BK120045-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: DG Spin
Cleared Date: 19-JUL-2013

BK120046-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24

Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: DG THERM
Cleared Date: 19-JUL-2013

BK130025-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: WADiana(R) Compact
Cleared Date: 30-AUG-2013

BK130067-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: Erytra(R)
Cleared Date: 17-JAN-2014

BK140101-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: DG Reader
Cleared Date: 21-MAY-2014

BK150266-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: DG Gel(R) 8 Neutral
Cleared Date: 28-JUL-2015

BK160100-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: DG Gel 8 Neutral
Cleared Date: 09-NOV-2016

BK170130-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: Erytra
Erytra
Cleared Date: 01-NOV-2017

BK180260-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24

Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: Erytra Eflexis
Cleared Date: 20-DEC-2018

BK180262-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: DG Gel 8 Neutral
Cleared Date: 20-DEC-2018

BK190318-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: Erytra
Cleared Date: 10-DEC-2019

BK190320-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: DG Reader
Cleared Date: 10-DEC-2019

BK190321-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: WADiana Compact
Cleared Date: 10-DEC-2019

BK190379-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: DG Reader Net
Cleared Date: 11-OCT-2019

BK200467-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: Erytra Eflexis
Cleared Date: 23-APR-2020

BK220738-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona

Parets Del Valles, SPAIN 08150
Trade Name: DG Reader Net
Cleared Date: 07-DEC-2022

BK220744-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: Blood Typing Manager
Cleared Date: 04-OCT-2022

BK220751-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: Erytra
Cleared Date: 01-NOV-2022

BK220752-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: Erytra Eflexis
Cleared Date: 01-NOV-2022

BK220753-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: DG Reader Net
Cleared Date: 01-NOV-2022

BK220754-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: DG Gel 8 Neutral
Cleared Date: 01-NOV-2022

BK230811-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150
Trade Name: Blood Typing Manager - 3.0
Cleared Date: 24-JUL-2023

BK230820-0 Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, SPAIN 08150

Trade Name: Erytra Eflexis - 3.0.0
Cleared Date: 22-JUN-2023

BK251182-0 Diagnostic Grifols, S.A.
Passeig Fluvial, 24
Parets del Valles, Barcelona SPAIN 08150
Trade Name: Erytra Eflexis (210600)
Cleared Date: 17-JUN-2025

BK251183-0 Diagnostic Grifols, S.A.
Passeig Fluvial, 24
Parets del Valles, Barcelona SPAIN 08150
Trade Name: Erytra (210400)
Cleared Date: 17-JUN-2025

BK251184-0 Diagnostic Grifols, S.A.
Passeig Fluvial, 24
Parets del Valles, Barcelona SPAIN 08150
Trade Name: DG Gel 8 Neutral (210393)
Cleared Date: 17-JUN-2025

BK261329-0 Diagnostic Grifols, S.A.
Passeig Fluvial, 24
Parets del Valles, Barcelona SPAIN 08150
Trade Name: Erytra Eflexis
Cleared Date: 21-MAY-2026

BK110036-0 Diaspect Medical GMBH
800 E. Leigh Street
Suite 206-5
Richmond, VA 23219
Trade Name: DiaSpect Hemoglobin T and DiaSpect
Hemoglobin Cuvettes
Cleared Date: 01-NOV-2011

BK120052-0 Diaspect Medical GMBH
800 E. Leigh Street
Suite 206-5
Richmond, VA 23219
Trade Name: DiaSpect Control HBT (-L, -M. -H)
Cleared Date: 14-NOV-2012

BK970013-0 Digi-Trax Corporation
1550 Barclay Boulevard
Buffalo Grove, IL 60089
Trade Name: Donor-ID
Cleared Date: 27-FEB-1998

BK000020-0 Digi-Trax Corporation
1550 Barclay Boulevard

Buffalo Grove, IL 60089
Trade Name: Digi-Trax Donor-ID - 2.0
Cleared Date: 20-APR-2000

BK010049-0 Digi-Trax Corporation
1550 Barclay Boulevard
Buffalo Grove, IL 60089
Trade Name: Donor-ID - 2.2
Cleared Date: 26-APR-2002

BK850006-0 Division of Immunologic Oncology
3900 Reservoir Rd.,NW,Box 63,Med-Den Bld
Washington, DC 20007
Trade Name: GTU DR/DQ Typing Tray
Cleared Date: 25-APR-1985

BK980009-0 Dominion Biologicals Limited
5 Isnor Drive
Dartmouth, Nova Scotia CANADA B3B1M1
Trade Name: Coombs Control Cells (IgG Coated)
Cleared Date: 30-OCT-1998

BK070065-0 Duley Hopkins and Associates
1200 Mountain Creek Road
215
Chattanooga, TN 37405
Trade Name: Blood Bank Information Management
System (BBIMS) - V2.05.01
Cleared Date: 25-APR-2008

BK090079-0 Duley Hopkins and Associates
1200 Mountain Creek Road
215
Chattanooga, TN 37405
Trade Name: Blood Bank Information Management
System (BBIMS V2.05.01)
Cleared Date: 13-JAN-2010

BK030056-0 Dynal Biotech Ltd
11 Bassendale Road
Croft Busines Park
Bromborough, Wirral, CH62 3QL, UNITED KINGDOM
Trade Name: Dynal Reli SSO HLA-A Typing Kit
Cleared Date: 29-JAN-2004

BK030057-0 Dynal Biotech Ltd
11 Bassendale Road
Croft Busines Park
Bromborough, Wirral, CH62 3QL, UNITED KINGDOM
Trade Name: Dynal Reli SSO HLA-B Typing Kit

Cleared Date: 29-JAN-2004

BK030058-0 Dynal Biotech Ltd
11 Bassendale Road
Croft Busines Park
Bromborough, Wirral, CH62 3QL, UNITED KINGDOM
Trade Name: DYNAL RELI SSO HLA-Cw Typing Kit
Cleared Date: 29-JAN-2004

BK030059-0 Dynal Biotech Ltd
11 Bassendale Road
Croft Busines Park
Bromborough, Wirral, CH62 3QL, UNITED KINGDOM
Trade Name: Dynal RELI SSO HLA-DQB1 Typing Kit
Cleared Date: 29-JAN-2004

BK030060-0 Dynal Biotech Ltd
11 Bassendale Road
Croft Busines Park
Bromborough, Wirral, CH62 3QL, UNITED KINGDOM
Trade Name: DYNAL RELI SSO HLA-DRB Typing
System.
Cleared Date: 29-JAN-2004

BK050012-0 Dynal Biotech Ltd
11 Bassendale Road
Croft Busines Park
Bromborough, Wirral, CH62 3QL, UNITED KINGDOM
Trade Name: Dynal RELI SSO HLA-DRB1 Typing Kit
-
For Use as a manual asssay or with
the AutoRELI Instrument
Cleared Date: 18-MAY-2005

BK960041-0 Dynamic Healthcare Technologies, Inc.
101 Southhall Lane, Suite 210
Maitland, FL 32751
Trade Name: Transfusion Service Mgr.
Cleared Date: 16-DEC-1997

BK840004-0 Dynatech Laboratories, Inc.
900 Slaters Lane
Alexandria, VA 22314
Trade Name: MicroBBank 220 Automated
Microplate Reader
Cleared Date: 18-MAY-1984

BK850013-0 Dynatech Laboratories, Inc.
900 Slaters Lane
Alexandria, VA 22314

Trade Name: MicroBank System
Cleared Date: 08-OCT-1985

BK840003-0 E.I. duPont de Nemours & Company
Medical Products Department
Wilmington, DE 19898
Trade Name: DuPont SCD
Cleared Date: 07-NOV-1984

BK910022-0 E.I. duPont de Nemours & Company
Medical Products Department
Wilmington, DE 19898
Trade Name: Du Pont Sorvall RC 3B Plus
Du Pont Sorvall RC 3C Plus
Centrifuge
Cleared Date: 21-JAN-1992

BK230958-0 EDONORSOFT LLC
1619 Whitfield Street
Sugarland, TX 77479
Trade Name: HemDonER 1.0.1
Cleared Date: 31-MAY-2024

BK840018-0 EK Industries, Inc.
411 Kay Avenue
Addison, IL 60101
Trade Name: Copper Sulfate Solution (for
women)
Cleared Date: 11-DEC-1984

BK840019-0 EK Industries, Inc.
411 Kay Avenue
Addison, IL 60101
Trade Name: Copper Sulfate Solution (for men)
Cleared Date: 11-DEC-1984

BK200520-0 EKF-diagnostic GmbH
Ebendorfer Chaussee 3
, Barleben GERMANY 39179
Trade Name: DiaSpect TM System
DiaSpect Tm
DiaSpect Tm Cuvettes
DiaSpectTM syster
Cleared Date: 24-NOV-2020

BK170138-0 ETHICON Inc.
Route 22 West
P.O. Box 151
Somerville, NJ 08876
Trade Name: EVICEL Laparoscopic Airless Spray

Accessory (35 cm Rigid)
Cleared Date: 26-JAN-2018

BK180287-0 ETHICON Inc.
Route 22 West
P.O. Box 151
Somerville, NJ 08876
Trade Name: VISTASEAL Airless Spray Accessory
Cleared Date: 10-APR-2019

BK190324-0 ETHICON Inc.
Route 22 West
P.O. Box 151
Somerville, NJ 08876
Trade Name: VISTASEAL Laparoscopic Dual Applicator (35 cm Rigid or 45 cm Flexible)
VISTASEAL Laparoscopic Dual Applicator (35 em Rigid or 45 em Flexible)
Cleared Date: 05-JUN-2019

BK251199-0 EUROMI S.A
11 rue des Nouvelles Technologies
ANDRIMONT, Belgium BELGIUM 4821
Trade Name: NLF system kit 2 (EUROMI)
Cleared Date: 10-NOV-2025

BK090044-0 Eclypsis Corporation
450 Lapp Road
Malvern, PA 19355
Trade Name: Sunrise Blood Bank version 2.0 SP2
Cleared Date: 13-NOV-2009

BK900006-0 Electrolux SARL
1317 F St. NW, suite 150
Washington, DC 20004
Trade Name: Blood Chain Thermostabilizer RCB42P
Cleared Date: 18-JUL-1990

BK190317-0 EmCyte Corporation
4331 Veronica South Shoemaker Blvd
For Myers, FL 33916
Trade Name: PurePRP SupraPhysiologic Concentrating System
Cleared Date: 12-FEB-2020

BK220719-0 EmCyte Corporation
4331 Veronica South Shoemaker Blvd

For Myers, FL 33916
Trade Name: Progenikine Concentrating Sytem 25
M System (K191564)
Cleared Date: 07-NOV-2019

BK860018-0 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA Plaza)
Tucson, AZ 85716
Trade Name: SEBRA Model 1150 (Blood Weigth
Monitor)
Cleared Date: 11-JUL-1986

BK860019-0 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA Plaza)
Tucson, AZ 85716
Trade Name: SEBRA Model 1300 (Tube Stripper)
Cleared Date: 29-SEP-1986

BK870023-0 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA Plaza)
Tucson, AZ 85716
Trade Name: Sebra Model #1500 Centrifuge Cup
Blood Bag Holder
Cleared Date: 25-SEP-1986

BK900025-0 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA Plaza)
Tucson, AZ 85716
Trade Name: SEBRA Model #2470, Mobile Tube
Sealer
Cleared Date: 26-JUN-1991

BK900026-0 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA Plaza)
Tucson, AZ 85716
Trade Name: SEBRA MODEL #1040, DIGITAL BLOOD
SHAKER/WEIGHT MONITOR
Cleared Date: 26-JUN-1991

BK900029-0 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA Plaza)
Tucson, AZ 85716
Trade Name: Sebra Model #2390, Mobile Tube
Sealer
Cleared Date: 26-JUN-1991

BK910015-0 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA Plaza)
Tucson, AZ 85716
Trade Name: Sebra Model #1290, Blood/Platelet

Coolant
Cleared Date: 11-SEP-1991

BK910024-0 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA Plaza)
Tucson, AZ 85716
Trade Name: SEBRA/MODEL #2100 TUBE SEALER
Cleared Date: 05-NOV-1992

BK910025-0 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA Plaza)
Tucson, AZ 85716
Trade Name: SEBRA MODEL 1440 BLD.
SHAKER/WT.MONITOR
Cleared Date: 05-NOV-1992

BK910026-0 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA Plaza)
Tucson, AZ 85716
Trade Name: SEBRA/MODEL 2590 HAND HELD TUBE
SEALER
Cleared Date: 05-NOV-1992

BK130037-0 Epic Systems Corporation
1979 Milky Way
Verona, WI 53593
Trade Name: Blood Product Administration
Module version 0.9
Cleared Date: 06-MAR-2014

BK170032-0 Epic Systems Corporation
1979 Milky Way
Verona, WI 53593
Trade Name: Blood Product Administration
Module, Version 2-2017
Cleared Date: 28-JUN-2017

BK200482-0 Epic Systems Corporation
1979 Milky Way
Verona, WI 53593
Trade Name: Blood Product Administration
Module
Cleared Date: 10-JUN-2020

BK241081-0 Epic Systems Corporation
1979 Milky Way
Verona, WI 53593
Trade Name: Blood Product Administration
Module (BPAM 4-2023)
Cleared Date: 21-AUG-2024

BK110035-0 Estar Technologies LTD
420 Lexington Avenue
Suite 2400
New York, NY 10170
Trade Name: TropoCells Autologous Platelet Preparation Kit
Cleared Date: 28-MAR-2012

BK920002-0 Ethox Corp.
251 Seneca St,
Buffalo, NY 14204
Trade Name: Ethox Transfer Pack
Cleared Date: 17-SEP-1992

BK830010-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Transfer Pack Unit(s) with Sterile Connector
Cleared Date: 23-AUG-1988
Cleared Under Travenol Laboratories

BK830011-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Closed Apheresis Kit for Extended Platelet Storage
Cleared Date: 27-MAY-1983
Cleared Under Travenol Laboratories

BK830009-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Plasma-Gard
Cleared Date: 25-JAN-1984
Cleared Under Travenol Laboratories

BK860015-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Apheresis Kit/Extended Plate. Stor. & Plas. Coll.
Cleared Date: 03-JUL-1986
Cleared Under Travenol Laboratories

BK860029-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Isoradial Separation Chamber

Cleared Date: 28-NOV-1986
Cleared Under Travenol Laboratories

BK860035-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: CS-3000 Bld Cell Separator Bld
Sample Containers
Cleared Date: 26-FEB-1987
Cleared Under Travenol Laboratories

BK870017-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Fenwal LS-300 Centrifuge
Cleared Date: 16-NOV-1987
Cleared Under Fenwal Laboratories

BK880023-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Fenual CS3000 Blood Cell Separator
Cleared Date: 13-JUN-1989
Cleared Under Travenol Laboratories

BK900005-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Closed System Apheresis Kit-
CS3000 Blood Cell Separator
Cleared Date: 05-JUN-1990
Cleared Under Baxter Healthcare Corporation

BK900016-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Closed System Apheresis Kit
CS-3000 Blood Cell Separator
(single venous access for platelet
collection)
Cleared Date: 07-JUN-1991
Cleared Under Baxter Healthcare Corporation

BK900020-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Optum Platelet Separation Chamber
Cleared Date: 07-NOV-1990
Cleared Under Baxter Healthcare Corporation

BK910014-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Sepacell R-200; Pre-Storage Leukocyte Depletion Set for Red Blood
Cleared Date: 18-SEP-1991
Cleared Under Baxter Healthcare Corporation

BK910032-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: OptiPress
Cleared Date: 03-JUN-1993
Cleared Under Baxter Healthcare Corporation

BK920003-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Fenwal Needle/Tube Sampling Protector/Safety Cover
Cleared Date: 12-MAR-1992
Cleared Under Baxter Healthcare Corporation

BK920029-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: 30-mL Collection Chamber for CS-3000 Plus Blood Cell Separator
Cleared Date: 06-MAY-1994
Cleared Under Baxter Healthcare Corporation

BK920032-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Sepacell Pre-storage Leukocyte Depletion Set for Red Cell
Cleared Date: 07-JUN-1993
Cleared Under Baxter Healthcare Corporation

BK920038-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Closed System Apheresis Kit with Integral Leukocyte Removal Filter
Cleared Date: 27-JUL-1994
Cleared Under Baxter Healthcare Corporation

BK930029-0 Fenwal Inc
Three Corporate Drive

Lake Zurich, IL 60047
Trade Name: AccessTM Management System (AMS)
Cleared Date: 20-JUN-1994
Cleared Under Baxter Healthcare Corporation

BK940005-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Fenwal Bone Marrow Collection Kit w/ Flexible Pre-filter and Inline Filters and Fenwal Bone Marrow Collection Stand
Cleared Date: 18-MAY-1994
Cleared Under Baxter Healthcare Corporation

BK940009-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Optipress TM Automated Blood Component
Cleared Date: 18-MAY-1994
Cleared Under Baxter Healthcare Corporation

BK940013-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Ex Storage PL 732 Containers w/ Sepacell Filter for Leukocytes Reduced Platelets
Cleared Date: 27-JUL-1994
Cleared Under Baxter Healthcare Corporation

BK940023-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Accessory Weight Scale for Medical Purposes
Cleared Date: 05-JUL-1994
Cleared Under Baxter Healthcare Corporation

BK940036-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Storage Containers for CS-3000 Apheresis Kit
Cleared Date: 27-DEC-1994
Cleared Under Baxter Healthcare Corporation

BK940040-0 Fenwal Inc
Three Corporate Drive

Lake Zurich, IL 60047
Trade Name: Sepacell PLS-10A,5A Leukocyte Reduction Filter Platelet Products
Cleared Date: 28-FEB-1995
Cleared Under Baxter Healthcare Corporation

BK940041-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Sepacell R-2000 Prestorage Leukocyte Reduction Set for Red Blood Cells
Cleared Date: 14-FEB-1995
Cleared Under Baxter Healthcare Corporation

BK950013-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: CS-3000 Plus (mononeuclear cells)
Cleared Date: 12-NOV-2002
Cleared Under Baxter Healthcare Corporation

BK950016-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Pall BPF4 Leukocyte Reduction Set for RBC
Cleared Date: 20-SEP-1995
Cleared Under Baxter Healthcare Corporation

BK950023-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: CS-3000 Blood Cell Separator Apheresis Kit
Cleared Date: 29-JUN-1995
Cleared Under Baxter Healthcare Corporation

BK960005-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Amicus Separator
Cleared Date: 19-DEC-1996
Cleared Under Baxter Healthcare Corporation

BK960083-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Hematype Segment Device
Cleared Date: 28-FEB-1997

Cleared Under Medical Safety Products, Inc.

BK980041-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Sepacell Pre-Storage Leukocyte Reduction Set for Red Cells
Cleared Date: 16-JUL-1999
Cleared Under Baxter Healthcare Corporation

BK990009-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Fenwal Amicus Separator Collection of Three Platelet Products
Cleared Date: 03-MAR-2000
Cleared Under Baxter Healthcare Corporation

BK000039-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Amicus Separator, Concurrent Collection of Red Blood Cells
Cleared Date: 26-AUG-2002
Cleared Under Baxter Healthcare Corporation

BK000047-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Amicus Separator, Mononuclear Cell Collection
Cleared Date: 31-JUL-2002
Cleared Under Baxter Healthcare Corporation

BK010016-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Apheresis Data Integration System (ADIS)
Cleared Date: 04-DEC-2001
Cleared Under Baxter Healthcare Corporation

BK010033-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Cygnet System
Cleared Date: 27-AUG-2002
Cleared Under Baxter Healthcare Corporation

BK020008-0 Fenwal Inc

Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: LeukoConnect - Pre-Storage Sterile
Connect Leukoreduction Set with
Sepacell Filter for Red Blood
Cells
Cleared Date: 10-DEC-2002
Cleared Under Baxter Healthcare Corporation - I.V. Systems Division

BK020056-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: ALYX System
Cleared Date: 20-DEC-2002
Cleared Under Baxter Healthcare Corporation

BK030085-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: ALYX Component Collection System
and Amicus Separator System
Cleared Date: 15-MAR-2004
Cleared Under Baxter Healthcare Corporation

BK040059-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Amicus Separator System
Cleared Date: 24-SEP-2004
Cleared Under Baxter Healthcare Corporation - Transfusion Therapies
Division

BK040084-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: ALYX Component Collection System
Cleared Date: 15-MAR-2005
Cleared Under Baxter Healthcare Corporation

BK050020-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: LeukoConnect - Pre-Storage Sterile
Connect Leukoreduction Set with
Sepacell Filter for Red Blood
Cells in additive solution
Cleared Date: 17-MAY-2005
Cleared Under Baxter Healthcare Corporation

BK050038-0 Fenwal Inc

Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: AMICUS Separator System
Cleared Date: 03-NOV-2005
Cleared Under Baxter Healthcare Corporation

BK060061-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: ALYX Component Collection System:
ALYX 2RBC-NLR Kit
Cleared Date: 09-FEB-2007
Cleared Under Baxter Healthcare Corporation

BK080024-0 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: ALYX Component Collection System
Cleared Date: 24-JUN-2008

BK080048-0 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: AMICUS Separator
Cleared Date: 02-OCT-2008

BK080053-0 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: ALYX Component Collection System
Cleared Date: 22-DEC-2008

BK090031-0 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: Bone Marrow Collection Kit and
Accessories
Cleared Date: 23-JUL-2009

BK090058-0 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: AMICUS Separator System
Cleared Date: 18-FEB-2010

BK090065-0 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: AMICUS Separator System
Cleared Date: 04-MAR-2010

BK100041-0 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: Autopheresis - C Plasmapheresis System
Cleared Date: 14-SEP-2017

BK100050-0 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: Autopheresis-C Plasmapheresis system
Cleared Date: 16-NOV-2010

BK100056-0 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: ALYX Component Collection System
Cleared Date: 07-DEC-2010

BK110025-0 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: Software, Blood Ban, Stand Alone
Cleared Date: 22-AUG-2011

BK110030-0 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: AMICUS Separator System with Software Version 4.3
Cleared Date: 23-DEC-2011

BK110066-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Product Sample Pack
Cleared Date: 27-FEB-2012

BK110072-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Aurora Plasmapheresis System
Plasmacell-C Disposable Set
Cleared Date: 29-MAR-2012

BK120082-0 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: AMICUS Apheresis Kits
AMICUS Separator System
Cleared Date: 08-JAN-2013

BK130004-0 Fenwal Inc
Three Corporate Dr
Lake Zurich, IL 60047
Trade Name: Alyx Component Collection System
Cleared Date: 11-SEP-2013

BK150236-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Alyx 2RBC Closed Disposable
Apheresis Kit
Alyx Component Collection System
(Alyx Classic)
Alyx Component Collection System
(Alyx by Fenwal)
Cleared Date: 22-APR-2015

BK170001-0 Fenwal Inc
Three Corporate Dr
Lake Zurich, IL 60047
Trade Name: Alyx Component Collection System
(Alyx Classic)
Alyx Component Collection System
(Alyx by Fenwal)
Alyx Component Collection System
(Fresenius Kabi)
Cleared Date: 03-APR-2017

BK200475-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: ALYX Component Collection System
Cleared Date: 10-JUN-2020

BK920026-0 Fenwal, Inc.
25212 W. Illinois Route 120, RLP-34
Round Lake, Il 60073
Round Lake, IL 60073
Trade Name: SDP Microplate Assay Management Software
Cleared Date: 30-JUL-1993
Cleared Under Genetic Systems Corporation

BK080018-0 Fenwal, Inc.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Amicus Separator System
Cleared Date: 26-AUG-2008
Cleared Under Fenwal Blood Technologies

BK080033-0 Fenwal, Inc.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: PLASMALINK
Cleared Date: 22-AUG-2008
Cleared Under Fenwal Blood Technologies

BK100044-0 Fenwal, Inc.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Amicus Separator System
Cleared Date: 30-JUL-2010
Cleared Under Fenwal Blood Technologies

BK120018-0 Fenwal, Inc.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: AMICUS Apheresis Kits
AMICUS Separator System
Cleared Date: 20-JUL-2012

BK120041-0 Fenwal, Inc.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: ALYX Component Collection System
AMICUS Separator System
Cleared Date: 03-OCT-2012

BK120047-0 Fenwal, Inc.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Autopheresis-C Plasmapheresis System
Plasmacell-C Set

Cleared Date: 18-DEC-2012

BK130030-0 Fenwal, Inc.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Alyx Component Collection System (
Alyx Classic)
Alyx Component Collection System (
Alyx by Fenwal)
Alyx Plasma Kit
Cleared Date: 01-NOV-2013

BK180296-0 Fidia Farmaceutici S.p.A.
Via Ponte della Fabbrica 3/A
, Abano Terme, Padua ITALY 35031
Trade Name: Fidia PRP Kit
Fidia PRP Kit - 20mL
Fidia PRP Kit - 50mL
Cleared Date: 05-NOV-2019

BK251299-0 Forever Labs, Inc
600 S Wagner Rd
Ann Arbor, MI 48103
Trade Name: PlateletQuick PRP
Cleared Date: 11-MAR-2026

BK190401-0 Fremon Scientific Inc
5726 La Jolla Blvd
La Jolla, CA 92037
Trade Name: ZipThaw 202
Cleared Date: 18-DEC-2019

BK160042-0 Fresenius Kabi
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Bone Marrow Collection Kit and
Stand
Cleared Date: 09-JUN-2016

BK170030-0 Fresenius Kabi
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Bone Marrow Collection Kit with
Flexible Pre-Filter and Inline
Filters
Bone Marrow Collection Stand
Cleared Date: 24-JUL-2017

BK160012-0 Fresenius Kabi AG
Else-Kroner-Strasse 1

Bad Homburg, GERMANY 61346
Trade Name: Aurora Plasmapheresis System,
Software Version 1.3
Cleared Date: 19-MAY-2016

BK160028-0 Fresenius Kabi AG
Three Corporate Dr
Lake Zurich, IL 60047
Trade Name: Aurora Xi Plasmapheresis System
Cleared Date: 21-SEP-2016

BK170057-0 Fresenius Kabi AG
Three Corporate Dr
Lake Zurich, IL 60047
Trade Name: Aurora Xi Plasmapheresis
System/Aurora Xi/Aurora Xi
system/Aurora Xi Software Version
1.1
Cleared Date: 25-AUG-2017

BK170072-0 Fresenius Kabi AG
Three Corporate Dr
Lake Zurich, IL 60047
Trade Name: DXT Data Management System
Cleared Date: 26-SEP-2017

BK180230-0 Fresenius Kabi AG
Three Corporate Dr
Lake Zurich, IL 60047
Trade Name: DXT Data Management System - 3.1
Cleared Date: 14-AUG-2018

BK180254-0 Fresenius Kabi AG
Three Corporate Dr
Lake Zurich, IL 60047
Trade Name: Glycerolyte 57 Solution, 400 mL
Glycerolyte 57 Solution, 500 mL
Cleared Date: 03-DEC-2018

BK180268-0 Fresenius Kabi AG
Three Corporate Dr
Lake Zurich, IL 60047
Trade Name: Aurora XI Plasmapheresis
System/Aurora XI System/Aurora XI
- 1.2
Cleared Date: 02-NOV-2018

BK180293-0 Fresenius Kabi AG
Three Corporate Dr
Lake Zurich, IL 60047

Trade Name: Plasmalink Bottle with Locking
Luer Adapter
Cleared Date: 21-DEC-2018

BK190362-0 Fresenius Kabi AG
Three Corporate Dr
Lake Zurich, IL 60047
Trade Name: Plasmalink Bottle with Locking
Luer Adapter
Cleared Date: 19-JUL-2019

BK190368-0 Fresenius Kabi AG
Else-Kroner-Strasse 1
Bad Homburg, GERMANY 61346
Trade Name: Aurora Plasmapheresis
System/Aurora /Aurora
system/Aurora Software Version
2.1/Aurora 2.1 - 2.1
Aurora Software Version 2.1
Upgrade Kit/Aurora Upgrade Kit -
2.1
Cleared Date: 26-JUL-2019

BK190413-0 Fresenius Kabi AG
Else-Kroner-Strasse 1
, Bad Homburg GERMANY 61352
Trade Name: CompoMaster Net G5 Plus - 9026551
CompoMat G5 Plus - 9026561
Cleared Date: 06-FEB-2020

BK190421-0 Fresenius Kabi AG
Else-Kroner-Strasse 1
Bad Homburg, GERMANY 61346
Trade Name: Fenwal Plasmalink Transfer Pack
Container with Luer Adapter and No
Outlet
Fenwal Plasmalink Transfer Pack
Container with Luer Adapter and No
Outlet Ports - 4R2088P
Cleared Date: 11-MAR-2020

BK200478-0 Fresenius Kabi AG
Else-Kroner-Strasse 1
Bad Homburg, GERMANY 61346
Trade Name: Aurora Xi Plasmapheresis
System/Aurora Xi/Aurora Xi
system/Aurora Xi - 1.2
Cleared Date: 07-MAY-2020

BK220785-0 Fresenius Kabi AG

Else-Kroner-Strasse 1
, Bad Homburg GERMANY 61352
Trade Name: Transfer Packs
Cleared Date: 20-DEC-2022

BK220788-0 Fresenius Kabi AG
Else-Kroner-Strasse 1
Bad Homburg, GERMANY 61346
Trade Name: Aurora Xi Plasmapheresis System
Cleared Date: 23-DEC-2022

BK230824-0 Fresenius Kabi AG
Else-Kroner-Strasse 1
Bad Homburg, GERMANY 61346
Trade Name: AMICUS Separator System
Cleared Date: 21-APR-2023

BK230825-0 Fresenius Kabi AG
Else-Kroner-Strasse 1
Bad Homburg, GERMANY 61346
Trade Name: ALYX 2RBC-LR Kit
ALYX Component Collection System
Cleared Date: 05-APR-2024

BK241135-0 Fresenius Kabi AG
Else-Kroner-Strasse 1
, Bad Homburg GERMANY 61352
Trade Name: Aurora Xi Plasmapheresis System
(6R4612, 6R4612R)
Cleared Date: 24-JAN-2025

BK251160-0 Fresenius Kabi AG
Else-Kroner-Strasse 1
Bad Homburg, GERMANY 61346
Trade Name: Adaptive Nomogram Bottle
Cleared Date: 21-FEB-2025

BK251289-0 Fresenius Kabi AG
Else-Kr ner-Str. 1
Bad Homburg, Hesse GERMANY 61352
Trade Name: Plasmacell-C Disposable Set
Cleared Date: 31-MAR-2026

BK110012-0 Fresenius Kabi USA LLC.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: CompoMat G5 and CompoMaster Net G5
System
Cleared Date: 02-AUG-2012
Cleared Under fresenius Kabi, LLC.

BK150242-0 Fresenius Kabi USA LLC.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Amicus Separator System
Cleared Date: 22-JUL-2015

BK150288-0 Fresenius Kabi USA LLC.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: AMICUS Apheresis Kits
AMICUS Apheresis System
Cleared Date: 28-AUG-2015

BK150357-0 Fresenius Kabi USA LLC.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: AMICUS Apheresis Kits (Model#
4R4580, 4R4580R)
AMICUS Separator System (Model#
4R2353, 4R2354)
Cleared Date: 20-APR-2016

BK160112-0 Fresenius Kabi USA LLC.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: AMICUS Separator System
Cleared Date: 07-APR-2017

BK170099-0 Fresenius Kabi USA LLC.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: AMICUS Separator System
AMICUS Separator System;
Refurbished
Cleared Date: 10-OCT-2017

BK190351-0 Fresenius Kabi USA LLC.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: ALYX 2RBC LR Kit
ALYX Component Collection System
ALYX RBC/Plasma Kit
ALYX Red Kit
Cleared Date: 06-JUN-2019

BK030022-0 Fresenius Medical Care North America
6675 185th Avenue NE
Suite 100
Redmond, WA 98052

Trade Name: Fresenius Compomat G4 &
Compomaster NT
Cleared Date: 11-JUL-2003
Cleared Under Fresenius Hemocare Inc.

BK040005-0 Fresenius Medical Care North America
95 Hayden Avenue
Lexington, MA 02420-9192
Trade Name: Fresenius Compoguard &
Donationmaster NT
Cleared Date: 26-MAR-2004
Cleared Under Fresenius Hemocare Inc.

BK040076-0 Fresenius Medical Care North America
95 Hayden Avenue
Lexington, MA 02420-9192
Trade Name: Compodock
Cleared Date: 17-DEC-2004
Cleared Under Fresenius Hemocare Inc.

BK880007-0 Fresenius USA/Seratronics Inc.
2637 Shadelands Drive
Walnut Creek, CA 94598
Trade Name: Fresenius AS104 Cell Separator
Cleared Date: 22-JUL-1996

BK880018-0 Fresenius USA/Seratronics Inc.
4090 Pike Lane
Concord, CA 94502
Trade Name: Astotherm IFT 200; IFT 220
Cleared Date: 25-AUG-1988

BK960066-0 Frigidaire Commercial Products Company
707 Robins St
Conway, AR 72032
Trade Name: Eagle Series Blood Storage
Refrigerator # ST30RGBB and ST50
Cleared Date: 30-AUG-1996

BK960092-0 Fujirebio America Inc.
30 Two Bridges Road
Suite 250
Fairfield, NJ 07004
Trade Name: Olympus PK CMV-PA System &
Controls
Cleared Date: 28-OCT-1998

BK960070-0 Fujirebio Diagnostics, Inc
201 Great Valley Parkway
Malvern, PA 19355

Trade Name: Olympus PK-TP System Control Set
Cleared Date: 19-JUN-1997
Cleared Under SCIMEDX Corporation

BK200476-0 Fujirebio Diagnostics, Inc
201 Great Valley Parkway
Malvern, PA 19355
Trade Name: PK CMV-PA System
PK CMV-PA System Control Set
Cleared Date: 19-OCT-2020

BK030007-0 Fujirebio Diagnostics, Inc.
201 Great Valley Parkway
Malvern, PA 19355
Trade Name: Olympus PK TP System
Cleared Date: 21-FEB-2003

BK060062-0 Fujirebio Diagnostics, Inc.
201 Great Valley Parkway
Malvern, PA 19355
Trade Name: Olympus PK TP Reagent System
Cleared Date: 25-JUN-2007

BK070030-0 Fujirebio Diagnostics, Inc.
201 Great Valley Parkway
Malvern, PA 19355
Trade Name: Olympus PK CMV-PA Test System and
Controls
Olympus PK7300 Automated Blood
Bank Analyzer
Cleared Date: 20-SEP-2007

BK940047-0 Fujirebio, Inc.
1129 Bloomfield Ave,
West Caldwell, NJ 07006
Trade Name: Olympus PK TP System Reactive
Control
Cleared Date: 29-NOV-1995

BK920005-0 Futuremed
2076 Deer Park Avenue
Deer Park, NY 11729
Trade Name: AM-4
Cleared Date: 29-SEP-1994

BK940055-0 Futuremed
2076 Deer Park Avenue
Deer Park, NY 11729
Trade Name: L Fusion Bags for Warming
Blood/Plasma w/ ANIMEC4

Cleared Date: 27-DEC-1994

BK050018-0 GE Medical Information Technologies
540 Northwest Highway
Barrington, IL 60010
Trade Name: Centricity Ultra Laboratory Transfusion Medicine (Ultra TM) - 4.0
Cleared Date: 13-JUN-2005

BK230807-0 GENESIS BIOLOGICS, INC.
16782 Von Karman Ave
Irvine, CA 92606
Trade Name: Adaptive Autologous Processing System
Cleared Date: 10-MAY-2023

BK220791-0 GPI USA, Inc.
4900 Woodway Dr, Suite 680
Houston, TX 77056
Trade Name: e-Delphyn Donor
Cleared Date: 26-JUN-2023

BK241042-0 Gale Force Aesthetics, LLC.
1644 Ramona Way
Alamo, CA 94507
Trade Name: Illuminate PRP
Cleared Date: 27-AUG-2024

BK870024-0 Gambro Inc.
23872 Kelsey Road
Barrington, IL 60010
Trade Name: Gambro Welding Device WD2
Cleared Date: 02-NOV-1987

BK820017-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Omni-Series Control
Cleared Date: 21-JAN-1983

BK830012-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma Omni Coombs Control Cells
Cleared Date: 13-JUN-1983

BK830014-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092

Trade Name: Elu-Kit II
Cleared Date: 13-JUN-2025

BK830019-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma Microtear System
Cleared Date: 21-SEP-1983

BK830026-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma Micro-U Plate
Cleared Date: 08-DEC-1983

BK850001-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma STS-M
Cleared Date: 05-APR-1985

BK850002-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma STS Red Cell Diluent
Cleared Date: 05-APR-1985

BK850005-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma STS-A
Cleared Date: 03-OCT-1986

BK850019-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma Micro-U Accessory Equipment
(Timer Device)
Cleared Date: 20-MAR-1986

BK850020-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma Micro-U Accessory Equipment
Cleared Date: 20-MAR-1986

BK850021-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma Micro-U Accessory Equipment

Cleared Date: 20-MAR-1986

BK850024-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma Micro-U Coombs Wash Solution
Cleared Date: 20-MAR-1986

BK850025-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma Micro-U Enhancement Reagent
Cleared Date: 20-MAR-1986

BK860024-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma N-HANCE
Cleared Date: 26-AUG-1986

BK880016-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: GammaZyme-B
Cleared Date: 25-AUG-1988

BK900021-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma-clone Control
Cleared Date: 26-OCT-1990

BK910001-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma Peg
Cleared Date: 24-MAR-1992

BK930026-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma RQC-Kit
Cleared Date: 16-NOV-1993

BK960055-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Coombs Control Cells (EIgG) Strong
Cleared Date: 23-OCT-1996

BK960056-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Coombs Control Cells (EIgG) Weak
Cleared Date: 23-OCT-1996

BK960077-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma Re-ACT Centrifuge
Cleared Date: 18-SEP-1997

BK960078-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma ReACT Incubator
Cleared Date: 18-SEP-1997

BK960079-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma ReACT Antibody Detection
Strips
Cleared Date: 18-SEP-1997

BK960080-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma ReACT Diluent
Cleared Date: 18-SEP-1997

BK960081-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma ReACT Control Cells (EIgG)
Cleared Date: 18-SEP-1997

BK960090-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma EGA Kit
Cleared Date: 19-MAY-2025

BK970002-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma-ReACT workstation
Cleared Date: 30-MAY-1997

BK970003-0 Gamma Biologicals, Inc.

3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma-ReACT Reader
Cleared Date: 30-MAY-1997

BK970047-0 Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Olympus System Control Reagent
Cleared Date: 11-DEC-1998

BK060050-0 Gaymar Industries, Inc.
1700 Pennsylvania Avenue, N.W.
Washington, DC 20006-4706
Trade Name: Medi-Temp III, Model FW600
Blood/Fluid Warmer
Cleared Date: 07-NOV-2006

BK950002-0 Gen Trak, Inc.
5100 Campus Dr.
Plymouth Meeting, NJ 19462
Trade Name: CQuentials DR DNA Typing Kit
Cleared Date: 15-MAY-1995

BK000051-0 Gen-Probe
10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name: The Chiron Procleix System
Cleared Date: 08-FEB-2002

BK010003-0 Gen-Probe
10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name: CHironProcleix HIV-1/HCV Controls
Cleared Date: 22-FEB-2002

BK010005-0 Gen-Probe
10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name: Chiron Procleix HIV/HCV
Proficiency Panel
Cleared Date: 01-OCT-2001

BK020045-0 Gen-Probe
10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name: Chiron Procleix System
Cleared Date: 21-NOV-2002

BK050007-0 Gen-Probe

10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name: Procleix System
Cleared Date: 29-APR-2005

BK050042-0 Gen-Probe
10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name: Procleix System for the Procleix WNV Assay
Cleared Date: 15-NOV-2005

BK060012-0 Gen-Probe
10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name: Procleix System
Cleared Date: 15-MAR-2006

BK060021-0 Gen-Probe
10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name: Procleix TIGRIS System for use with the Procleix WNV Assay
Cleared Date: 20-FEB-2007

BK110002-0 Gen-Probe
550 West Avenue
Stanford, CT 06902
Trade Name: LIFECODES HLA-A eRES Typing Kit for use with Luminex
LIFECODES HLA-B eRES Typing Kit for use with Luminex
LIFECODES HLA-DRB 3, 4, 5 Typing Kit for use with Luminex
LIFECODES HLA-DRB1 eRES Typing Kit for use with Luminex
Cleared Date: 02-DEC-2011

BK120063-0 Gen-Probe
550 West Avenue
Stanford, CT 06902
Trade Name: LIFECODES HLA-C eRES Typing Kit for use with Luminex
Cleared Date: 21-NOV-2012

BK040019-0 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: Antibody Monitoring System Class I and Class II (AMS1 and AMS1+2)

Cleared Date: 06-JUL-2004
Cleared Under GTI, INC

BK040034-0 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: Lifecodes LifeScreen: A Luminex 100 Screening Assay for the Detection of IgG Antibodies to HLA Class I and Class II Molecules of Human Origin
Cleared Date: 16-JUL-2004
Cleared Under GTI, INC

BK040035-0 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: Lifecodes ID Class I: A Luminex 100 screening assay for the qualitative detection of IgG panel reactive antibodies (PRA) to HLA Class I molecules
Lifecodes ID Class II: A Luminex 100 screening assay for the qualitative detection of IgG panel reactive antibodies (PRA) to HLA Class II molecules
Cleared Date: 16-JUL-2004
Cleared Under GTI, INC

BK050040-0 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: ThromboType (HPA 1-6, 15) and ThromboType 1 (HPA 1)
Cleared Date: 20-JAN-2006
Cleared Under GTI, INC

BK050054-0 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: GranType(TM)
Cleared Date: 02-MAR-2006
Cleared Under GTI, INC

BK060038-0 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: MICROAMS
Cleared Date: 28-JUL-2006

Cleared Under GTI, INC

BK070034-0 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: HLA EZ Type
Cleared Date: 10-JUL-2008
Cleared Under GTI, INC

BK070045-0 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: Donor Screen HLA Class I and Class II
Cleared Date: 30-JUL-2008
Cleared Under GTI, INC

BK110011-0 Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: Lifecodes Class II ID v2
Cleared Date: 04-JUN-2012

BK220714-0 Genesis Biosystems Inc.
1500 Eagle Court
Lewisville, TX 75057
Trade Name: LipiVage (K172714)
Cleared Date: 08-DEC-2017

BK850003-0 GenesisBPS, LLC
65 Commerce Way
Hackensack, NJ 07601
Trade Name: Cryosan Pediatric Pack
Cleared Date: 05-APR-1985
Cleared Under Cryosan Inc.

BK950018-0 GenesisBPS, LLC
65 Commerce Way
Hackensack, NJ 07601
Trade Name: TOTAL CONTAINMENT DEVICE (TCD)
Cleared Date: 14-NOV-1995
Cleared Under DENCO, INC.

BK140187-0 GenesisBPS, LLC
465 State Route 17
Ramsey, NJ 07446
Trade Name: Blade Arm Module
Genesis Rapid Weld STW
Weld Blade Module Replacement Kits
Cleared Date: 06-MAR-2015

Cleared Under Genesis BPS, LLC

BK210584-0 GenesisBPS, LLC
465 State Route 17
Ramsey, NJ 07446
Trade Name: 1000 Weld Blade Module Replacement Kit
250 Weld Blade Module Replacement Kit
500 Weld Blade Module Replacement Kit
Blade Arm Module
Genesis RapidWeld II STW (Sterile Tube Welder), model GRW-430-02
Genesis RapidWeld II STW, model GRW-430-02
Power Supply
Cleared Date: 15-JUL-2022

BK880025-0 Genetic Design Inc.
7019 Albert Pick Rd.; Suite H
Greensboro, NC 27409
Trade Name: HLA-DR Typing Trays
Cleared Date: 30-DEC-1988

BK870006-0 Genetic Systems Corporation
3005 First Avenue
Seattle, WA 98121
Trade Name: HLA-B27 Antigen Typing Kit
Cleared Date: 20-JUL-1987

BK900011-0 Genetic Systems Corporation
3005 First Avenue
Seattle, WA 98121
Trade Name: Genetic Systems Blood Virus Software
Cleared Date: 15-MAR-1991

BK930031-0 Genetic Systems Corporation
3005 First Avenue
Seattle, WA 98121
Trade Name: Expresso Cartridge Software for Blood Virus Applications
Cleared Date: 24-FEB-1994

BK860022-0 Genetic Testing Institute
1701 W. Wisconsin Avenue, Suite 429
Milwaukee, WI 53233
Trade Name: GTI-60 HLA Typing Trays
GTI-72 HLA Typing Trays

GTI-96 HLA Typing Trays
Cleared Date: 24-FEB-1987

BK910013-0 Genetic Testing Institute
1701 W. Wisconsin Avenue, Suite 429
Milwaukee, WI 53233
Trade Name: GTI Pep Antibody Enhancement Solution
Cleared Date: 23-JUN-1992

BK930014-0 Genetic Testing Institute
1701 W. Wisconsin Avenue, Suite 429
Milwaukee, WI 53233
Trade Name: GTI Reduced Wash Elution Kit
Cleared Date: 28-OCT-1993

BK930032-0 Genetic Testing Institute
1701 W. Wisconsin Avenue, Suite 429
Milwaukee, WI 53233
Trade Name: GTI ACE Antigen Capture ELISA for Detection of IgG Antibodies to Platelet Specific Antibodies
Cleared Date: 20-JUN-1994

BK950004-0 Genetic Testing Institute
1701 W. Wisconsin Avenue, Suite 429
Milwaukee, WI 53233
Trade Name: GTI-PAK 2 Platelet Antibody Screening Kit
Cleared Date: 15-MAY-1995

BK950005-0 Genetic Testing Institute
1701 W. Wisconsin Avenue, Suite 429
Milwaukee, WI 53233
Trade Name: GTI-HLA 1, Class I Antibody Screening Kit
Cleared Date: 19-MAY-1995

BK970006-0 Genetic Testing Institute
1701 W. Wisconsin Avenue, Suite 429
Milwaukee, WI 53233
Trade Name: GTI-HAT, Heparin-Associated Antibody Screening Kit
Cleared Date: 14-APR-1997

BK980005-0 Genetic Testing Institute
150 N. Patrick Blvd.
Brookfield, WI 53045
Trade Name: GTI PAT HPA-1 (PI) Genotyping Kit
Cleared Date: 23-APR-1999

BK000015-0 Genetic Testing Institute
150 N. Patrick Blvd.
Brookfield, WI 53045
Trade Name: Quick ID Solid Phase ELISA for detection of Panel Reactive HLA Class I IgG Antibodies (PRA)
Cleared Date: 17-OCT-2000

BK000031-0 Genetic Testing Institute
150 N. Patrick Blvd.
Brookfield, WI 53045
Trade Name: GTI-MACE (Modified Capture Elisa)
Cleared Date: 29-JAN-2001

BK990043-0 Genetic Testing Institute
150 N. Patrick Blvd.
Brookfield, WI 53045
Trade Name: B-Screen Solid Phase ELISA Assay for Detection of IgG Antibodies to HLA Class II Antigens
Cleared Date: 02-OCT-2000

BK010010-0 Genetic Testing Institute
150 N. Patrick Blvd.
Brookfield, WI 53045
Trade Name: Quik-ID Class II
Cleared Date: 01-OCT-2001

BK960059-0 Genetic Testing Institute, Inc. (GTI)
20925 Crossroads Circle
Sutie 200
Waukesha, WI 53186
Trade Name: PAKAUTO Platelet Antibody Screening Kit
Cleared Date: 22-OCT-1998
Cleared Under Genetic Testing Institute

BK090002-0 Genetic Testing Institute, Inc. (GTI)
20925 Crossroads Circle
Sutie 200
Waukesha, WI 53186
Trade Name: Lifecodes LifeScreen Deluxe
Cleared Date: 17-APR-2009

BK150354-0 Genteel LLC
4011 Livingston St
Midland, TX 79709
Trade Name: Genteel Lancing Device (Genteel)
Cleared Date: 18-DEC-2015

BK940057-0 George-King Bio-Medical, Inc.
11771 W 112th St,
Overland Park, KS 66210
Trade Name: B-Fact, Borderline Factor Assay Control
Cleared Date: 14-NOV-1994

BK940058-0 George-King Bio-Medical, Inc.
11771 W 112th St,
Overland Park, KS 66210
Trade Name: A-Fact, Abnormal Factor Assay Control
Cleared Date: 14-NOV-1994

BK940059-0 George-King Bio-Medical, Inc.
11771 W 112th St,
Overland Park, KS 66210
Trade Name: Positive Lupus Anticoagulant Plasma
Cleared Date: 14-NOV-1994

BK940060-0 George-King Bio-Medical, Inc.
11771 W 112th St,
Overland Park, KS 66210
Trade Name: Protein C Deficient Plasma
Cleared Date: 14-NOV-1994

BK050026-0 Greiner Bio One North America, Inc.
4238 Capital Drive
Monroe, NC 28110
Trade Name: Greiner Vacuette No Additive Tubes
Cleared Date: 07-JUL-2005

BK050028-0 Greiner Bio One North America, Inc.
4238 Capital Drive
Monroe, NC 28110
Trade Name: Greiner Vacuette Clot Activator Tube
Cleared Date: 07-JUL-2005

BK030001-0 Greiner Bio-One GmbH
4238 Capital Drive
Monroe, NC 28112
Trade Name: Greiner Vacuette EDTA K3 Tube
Cleared Date: 26-FEB-2003

BK030032-0 Greiner Bio-One GmbH
4238 Capital Drive
Monroe, NC 28112

Trade Name: Vacuette EDTA K2 Tube
Cleared Date: 18-JUL-2003

BK040066-0 Greiner Vacuette North America, Inc.
4238 Capital Dr
Monroe, NC 28110
Trade Name: Greiner VACUETTE No Additive Evacuated Blood Collection Tubes and Serum Clot Activator Blood Collection Tubes
Cleared Date: 10-SEP-2004
Cleared Under sienna partners

BK251245-0 Grifols Diagnostic Solutions Inc.
10808 Willow Court
San Diego, CA 92127
Trade Name: Procleix WNV/Babesia Quality Control
Cleared Date: 02-JAN-2026

BK251246-0 Grifols Diagnostic Solutions Inc.
10808 Willow Court
San Diego, CA 92127
Trade Name: Procleix HIV-1/HCV/HBV Quality Control (N/A)
Cleared Date: 02-JAN-2026

BK251300-0 Grifols Diagnostic Solutions Inc.
10808 Willow Court
San Diego, CA 92127
Trade Name: Procleix Plasmodium Quality Control
Cleared Date: 26-MAR-2026

BK231025-0 HOLOGIC INC
10210 Genetic Center Dr
San Diego, CA 92121
Trade Name: Aptima HIV-1 Quant Dx Assay
Cleared Date: 06-AUG-2024

BK220691-0 HUMAN MED AG
Wilhelm-Hennemann-Strasse 9
, Schwerin GERMANY D-19061
Trade Name: LIPCOLLECTOR II (K101713)
Cleared Date: 29-JUN-2010

BK200449-0 Haeleon Medical, Inc.
1090 Lawrence Dr
Newbury Park, CA 91320
Trade Name: Healeon Duet

Cleared Date: 06-AUG-2020

BK840002-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Alpha Plasma Pooling Bottle II
Cleared Date: 13-JUL-1984

BK840007-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Alpha Plasma Pooling Bottle
Cleared Date: 21-SEP-1984

BK840014-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics V50 Surge Procedure
Cleared Date: 06-JUL-1984

BK840021-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics PCS Plasma Collection System
Cleared Date: 03-JAN-1985

BK840022-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics 115 Cell Washer
Cleared Date: 24-OCT-1984

BK840025-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics 16 Programmed Pump
Cleared Date: 14-NOV-1984

BK860013-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: 603-EX Extended Storage Plateletpheresis Set
Cleared Date: 06-NOV-1987

BK870026-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics Ultralite Plasma

Collection System
Cleared Date: 17-MAR-1988

BK890007-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics 705 Time Saver
Platelet Pack
Cleared Date: 13-AUG-1990

BK900019-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Alpha Plasma Pooling Bottle II
(Significant Rev.)
Cleared Date: 14-AUG-1990

BK900022-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Plasma Pooling Bottle II
(Significant Revision)
Cleared Date: 11-OCT-1990

BK900027-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: 790 ESP Collection Set
Cleared Date: 19-APR-1991

BK910009-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Alpha Plasma Pooling Bottle II
(Significant Rev.)
Cleared Date: 08-SEP-1991

BK920012-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: 705FTSPP/790F
Cleared Date: 16-SEP-1992

BK920039-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Plasma Collection System PCS2
Cleared Date: 02-SEP-1993

BK930007-0 Haemonetics Corporation

400 Wood Road
Braintree, MA 02184-9114
Trade Name: 790 Extended Storage Platelet
Collection Set
Cleared Date: 16-NOV-1993

BK930008-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: 791 A Fresh Frozen Plasma
Collection Set (Latham Bowl)
Cleared Date: 16-NOV-1993

BK930009-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: 791 Fresh Frozen Plasma Collection
Set (Blow Molded Bowl)
Cleared Date: 16-NOV-1993

BK930013-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: MCS Plus & Disp.Sets, List No.
890,790,791A,791
Cleared Date: 12-JAN-1994

BK940064-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Red Cell and Plasma Apheresis
Set/FOR USE WITH MCP PLUS
Cleared Date: 23-OCT-1995

BK950001-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics RBC Apheresis Set for
MCS+(NO.831)
Cleared Date: 22-APR-1996

BK950006-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: List #890F Extended Storage Plt
Collection Set
Cleared Date: 09-JUN-1995

BK950007-0 Haemonetics Corporation
400 Wood Road

Braintree, MA 02184-9114
Trade Name: ESP White Cell Filter (No. 790F)
Cleared Date: 28-JUN-1995

BK950033-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics PCS2
Cleared Date: 16-APR-1996

BK950034-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Double Product Collection (SDP-3)
Cleared Date: 15-FEB-1996

BK950063-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Red Blood Cell and Plasma
Collection Set for the MCS Plus
#823
Cleared Date: 22-JUL-1996

BK960006-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Double Unit Red Blood Cell
Aphersis Set MCS #833
Cleared Date: 15-OCT-1996

BK960022-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: MCS+Double Unit RBC Apheresis
Set-Dry(LN832)
Cleared Date: 16-APR-1997

BK960023-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: MCS+Red Cell & Plasma Apheresis
Set - Dry(LN822)
Cleared Date: 16-APR-1997

BK960095-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: MCS+Apheresis System (LN8150)
Cleared Date: 11-APR-1997

BK970029-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Alpha Plasma Pooling Bottle II
(60-2227S)
Cleared Date: 07-JAN-1998
Cleared Under Alpha Therapeutic Corporation

BK970034-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: LN994CF
Cleared Date: 15-SEP-1998

BK970041-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics Corp. Extended Storage
Platelet & Plasma Apheresis Set
with Saline Compensation & Pall
LRF-XL (LN994C)
Cleared Date: 16-NOV-1998

BK980040-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Citroflex Plalsticized PVC
Extended Storage Platelet Bag
Cleared Date: 07-JAN-1999

BK000002-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Model 215 Automated
Glycerolization and
Deglycerolization System
Cleared Date: 04-MAY-2001

BK990033-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: MCS+ LN8150
Cleared Date: 20-JAN-2000

BK990044-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics LN832F
Two Unit Red Cells Disposable Set

with Leukocyte reduction Filter
Cleared Date: 27-OCT-2000

BK000048-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics LN832F
Cleared Date: 09-APR-2001

BK010035-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: MCS+ Mobile Collection System
Cleared Date: 20-DEC-2002

BK020001-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Plasma Pooling Bottle II
Cleared Date: 29-MAR-2002

BK030031-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics Model 215 Automated
Glycerolyzation /
Deglycerolyzationand Cell Washing
System
Cleared Date: 10-SEP-2003

BK030062-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics Model 215 Automated
Glycerolization/deglycerolization
System
Cleared Date: 10-DEC-2003

BK030084-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics LN994CF-CPP-BA
Extended Storage Platelet and
Plasma Apheresis Set
Cleared Date: 09-JAN-2004

BK040001-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics 4mL Sampling System

Cleared Date: 27-FEB-2004

BK040020-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics LN994CF-BA Extended Storage Platelet and Plasma Apheresis Set with Leukocyte Reduction Filter, and 4 mL Sampling System.
Cleared Date: 29-MAR-2004

BK040025-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: PCS2 Plasma Collection System
Cleared Date: 02-JUN-2004

BK040041-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics MCS+8150 Apheresis System
Cleared Date: 12-JUL-2004

BK040077-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics Model 215 Automated Glycerolization/Deglycerolization System
Cleared Date: 21-DEC-2004

BK050006-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: ACP 215 Glycerolization/Deglycerolization System
Cleared Date: 14-APR-2005

BK050047-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: MCS+9000, SDP revision E software, 994CF-CPP series disposable sets
Cleared Date: 21-NOV-2005

BK050048-0 Haemonetics Corporation
400 Wood Road

Braintree, MA 02184-9114
Trade Name: Haemonetics MCS+ 8150 Apheresis System
Cleared Date: 27-SEP-2005

BK060008-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics ACP 215 Glycerolization/Deglycerolization System
Cleared Date: 23-MAY-2006

BK060023-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics MCS+ 8150 Apheresis System
Cleared Date: 23-MAY-2006

BK060033-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics PCS 2 Plasma Collection System, Wireless (W) Capable Modification-
Cleared Date: 27-MAR-2008

BK060057-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Cymbal Automated Blood Collection System
Cleared Date: 28-FEB-2007

BK070019-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics PCS2 Plasma Collection System
Cleared Date: 23-MAY-2007

BK080025-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Cymbal Automated Blood Collection System
Cleared Date: 15-AUG-2008

BK090041-0 Haemonetics Corporation

400 Wood Road
Braintree, MA 02184-9114
Trade Name: Symphony System
Cleared Date: 28-SEP-2009

BK090083-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Cymbal Automated Blood Collection System
Cleared Date: 27-JAN-2010

BK110015-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Nextgen - 1.0.0
Cleared Date: 13-JUN-2011

BK120065-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: PCS2 Plasma Collection System
Cleared Date: 26-NOV-2012

BK120083-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: MCS+ 8150 System - Wireless
Cleared Date: 20-MAR-2013

BK120084-0 Haemonetics Corporation
4925 Robert J Mathews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: Phlebotomy System
Cleared Date: 30-APR-2013

BK130056-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics PCS2 Plasma Collection System
Cleared Date: 29-AUG-2014

BK130081-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Cymbal Automated Blood Collection System
Cleared Date: 23-JAN-2014

BK130082-0 Haemonetics Corporation
4925 Robert J Mathews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: NextGen
Cleared Date: 08-AUG-2014

BK140108-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: MCS+ 8150
Cleared Date: 26-AUG-2014

BK140199-0 Haemonetics Corporation
4925 Robert J Mathews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: Surround 5.1
Cleared Date: 05-FEB-2015

BK150287-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics MCS+ 8150 Apheresis System
Cleared Date: 28-JUL-2015

BK150292-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics PCS2 Plasma Collection System
Cleared Date: 28-JUL-2015

BK150360-0 Haemonetics Corporation
4925 Robert J Mathews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: SafeTrace Tx 3.12.0 Device
Cleared Date: 11-MAR-2016

BK160019-0 Haemonetics Corporation
4925 Robert J Mathews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: ElDorado Donor 4 Next Generation Donor Management Solution 1.0.0
Cleared Date: 17-MAY-2016

BK160052-0 Haemonetics Corporation
4925 Robert J Mathews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: InstaMatch 1.0.0
Cleared Date: 25-AUG-2016

BK170045-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: PCS 300 Plasma Collection System
Cleared Date: 25-JUL-2017

BK180185-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: PCS 300 Plasma Collection System
Cleared Date: 27-MAR-2018

BK180209-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Safe Trace Tx - 4.0.0
SafeTrace Tx
Cleared Date: 07-AUG-2018

BK200498-0 Haemonetics Corporation
125 Summer St
Boston, MA 02110
Trade Name: NexSys PCS Plasma Collection
System with Persona Technology
Cleared Date: 02-OCT-2020

BK220798-0 Haemonetics Corporation
125 Summer St
Boston, MA 02110
Trade Name: NexSys PCS Plasma Collection
System with ExpressPlus Technology
Cleared Date: 20-JUN-2023

BK231036-0 Haemonetics Corporation
125 Summer St
Boston, MA 02110
Trade Name: NexLynk DMS Donor Management
System - 4.10.0
Cleared Date: 15-MAR-2024

BK241062-0 Haemonetics Corporation
125 Summer St
Boston, MA 02110

Trade Name: BloodTrack Software - 4.16.0
Cleared Date: 21-JUN-2024

BK251241-0 Haemonetics Corporation
125 Summer St
Boston, MA 02110
Trade Name: SafeTrace Tx - 5.0.0
Cleared Date: 10-SEP-2025

BK251292-0 Haemonetics Corporation
125 Summer St
Boston, MA 02110
Trade Name: NexSys PCS Plasma Collection System with Persona Plus Technology
Cleared Date: 20-FEB-2026

BK080001-0 Haemonetics Corporation Software Solutions
1630 Industrial Park Street
Covina, CA 91722-9144
Trade Name: PCS2 Plasma Collection System_Revision K software
Cleared Date: 28-MAY-2008
Cleared Under Haemonetics Corporation

BK080038-0 Haemonetics Corporation Software Solutions
1630 Industrial Park Street
Covina, CA 91722-9144
Trade Name: MCS+ 9000 System
Cleared Date: 04-SEP-2008
Cleared Under Haemonetics Corporation

BK090004-0 Haemonetics Corporation Software Solutions
1630 Industrial Park Street
Covina, CA 91722-9144
Trade Name: MCS+8150 System - Wireless
Cleared Date: 20-FEB-2009
Cleared Under Haemonetics Corporation

BK140133-0 Haemonetics Corporation Software Solutions
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: BloodTrack - 4.7.0
Cleared Date: 29-AUG-2014

BK140166-0 Haemonetics Corporation Software Solutions
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762

Trade Name: Cross Donation Check System (CDCS)
- 1.0.0
Cleared Date: 10-OCT-2014

BK140183-0 Haemonetics Corporation Software Solutions
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: Donor Doc 3.0.0
Cleared Date: 10-DEC-2014

BK150308-0 Haemonetics Corporation Software Solutions
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: ElDorado Donor - 3.0.0
Cleared Date: 20-NOV-2015

BK150330-0 Haemonetics Corporation Software Solutions
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: NextGen 3.0.0
Cleared Date: 03-MAR-2016

BK820014-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Plasma Pooling Bags
Cleared Date: 13-JUN-2025
Cleared Under Cutter Biological

BK840010-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: CLX Transfer Bag
Cleared Date: 15-AUG-1984
Cleared Under Cutter Biological

BK850026-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Neocel System
Cleared Date: 22-MAY-1986
Cleared Under Miles, Inc.

BK860001-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Leukotrap System

Cleared Date: 05-AUG-1986
Cleared Under Cutter Biological

BK860006-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Cutter PPP Harness
Cleared Date: 17-SEP-1986
Cleared Under Miles, Inc.

BK860028-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Component Aliquot System
Cleared Date: 07-DEC-1987
Cleared Under Miles, Inc.

BK860040-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Blood Collection Unit w/o
Anticoagulant
Cleared Date: 24-JUN-1987
Cleared Under Cutter Biological

BK900034-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Phlebotomist Protection Device
Cleared Date: 27-JAN-1992
Cleared Under Miles, Inc.

BK920027-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Plasma Pooling Bag
Cleared Date: 13-APR-1993
Cleared Under Miles, Inc.

BK930001-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Plasma Sample Vial
Cleared Date: 20-SEP-1993
Cleared Under Miles, Inc.

BK970040-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Medsep Plasma Bag

Cleared Date: 23-JAN-1998
Cleared Under MEDSEP Corp.

BK000032-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Modified Plasma Bag
Cleared Date: 27-SEP-2000
Cleared Under MEDSEP Corp.

BK020014-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Bacterial Detection System
(BDS)
Cleared Date: 22-OCT-2002
Cleared Under Medsep Corporation

BK030082-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall eBDS
Cleared Date: 04-FEB-2004
Cleared Under Medsep Corporation

BK050015-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Leukotrap SC RC Filtration System
Cleared Date: 14-APR-2005
Cleared Under MEDSEP Corp.

BK050034-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Acrodose PL System, Platelet
Pool and Store Set with eBDS
Pall Platelet Pool and Store Set
with Pall eBDS
Cleared Date: 28-SEP-2005
Cleared Under Medsep Corporation

BK050074-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Acrodose PL System
Cleared Date: 26-JAN-2006
Cleared Under Medsep Corporation

BK050075-0 Haemonetics Manufacturing Inc.

400 Wood Road
Braintree, MA 02184
Trade Name: Pall eBDS
Cleared Date: 20-DEC-2005
Cleared Under Medsep Corporation

BK060040-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Acrodose PL System, Platelet
Pool and Store Set with in-line
Leukocyte Reduction Filter
Cleared Date: 12-APR-2007
Cleared Under Medsep Corporation

BK060044-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Acrodose PL System, Platelet
Pool and Store Set with eBDS
Cleared Date: 01-SEP-2006
Cleared Under Medsep Corporation

BK060045-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Acrodose PL System, Platelet
Pool and Store Set
Cleared Date: 01-SEP-2006
Cleared Under Medsep Corporation

BK060047-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall eBDS
Cleared Date: 04-APR-2007
Cleared Under Medsep Corporation

BK070004-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall eBDS
Cleared Date: 26-JUN-2007
Cleared Under Medsep Corporation

BK070056-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Acrodose PLus System Platelet
Pool and Store Set with in-line

Leukocyte Reduction Filter and
eBDS
Cleared Date: 27-SEP-2007
Cleared Under Medsep Corporation

BK070057-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Acrodose PLus System Platelet
Pool and Store Set with in-line
Leukocyte Reduction Filter
Cleared Date: 27-SEP-2007
Cleared Under Medsep Corporation

BK070063-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall eBDS
Cleared Date: 26-JAN-2008
Cleared Under Medsep Corporation

BK080003-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Acrodose PLus System,
Platelet Pool and Store Set with
in-Line Leukocyte Reduction Filter
Cleared Date: 18-APR-2008
Cleared Under MEDSEP Corporation

BK090007-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Acrodose PL System
Cleared Date: 25-FEB-2009
Cleared Under Medsep Corporation

BK160027-0 Haemonetics Manufacturing Inc.
1630 Industrial Park Street
Covina, CA 91722
Trade Name: Acrodose PL System
Cleared Date: 16-MAY-2016

BK000037-0 Harvest Technologies Corp
40 Grissom Road
Plymouth, MA 02360
Trade Name: Harvest PRP Separation System
Cleared Date: 05-FEB-2001
Cleared Under Harvest Technologies

BK100059-0 Harvest Technologies Corp
40 Grissom Road
Plymouth, MA 02360
Trade Name: Harvest PRP Separation System
Cleared Date: 18-NOV-2010
Cleared Under Harvest Technologies

BK120038-0 Harvest Technologies Corp
40 Grissom Road
Plymouth, MA 02360
Trade Name: Harvest PRP Separation System with ACDA(30mL)

Cleared Date: 28-SEP-2012
Cleared Under Harvest Technologies

BK130068-0 Harvest Technologies Corp
40 Grissom Road
Plymouth, MA 02360
Trade Name: SmartPrep2 System
Cleared Date: 24-MAR-2014
Cleared Under Harvest Technologies

BK220696-0 Harvest Technologies Corp
40 Grissom Road
Plymouth, MA 02360
Trade Name: ADIPREP ADIPOSE TRANSFER SYSTEM (K121005)
Cleared Date: 21-SEP-2012

BK200526-0 Headspring Healthcare, Inc
10415 Morado Circle
Austin, TX 78759
Trade Name: NDDR and CDCS
Cleared Date: 18-NOV-2020

BK170136-0 Healeon Medical, Inc.
1111 Rancho Conejo Blvd #204
Newbury Park, CA 91320
Trade Name: Healeon PRP Platelet Preparation System
Cleared Date: 20-NOV-2018

BK050001-0 Healthcare Management Systems, Inc.
3102 West End Avenue, Suite 400
Nashville, TN 37203
Trade Name: Monitor Blood Administration Module - Release 24.0
Cleared Date: 28-SEP-2005

BK090025-0 Healthcare Management Systems, Inc.
3102 West End Avenue, Suite 400
Nashville, TN 37203
Trade Name: HMS Blood Administration Module,
Release 8.0
Cleared Date: 04-MAR-2010

BK030049-0 Healthcare-ID, Inc.
1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name: Donor-ID - version 2.5
Cleared Date: 31-OCT-2003
Cleared Under Healthcare-ID

BK060058-0 Healthcare-ID, Inc.
1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name: Donor-ID - 3.0
Cleared Date: 08-FEB-2007
Cleared Under Healthcare-ID

BK080044-0 Healthcare-ID, Inc.
1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name: Donor-ID Web - 3.1.4
Cleared Date: 10-JUN-2009
Cleared Under Healthcare-ID

BK120030-0 Healthcare-ID, Inc.
1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name: Donor-ID Web (TM) 3.2
Cleared Date: 25-JUN-2012
Cleared Under Healthcare-ID

BK140149-0 Healthcare-ID, Inc.
1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name: Donor-ID TM version 3.2.6
Cleared Date: 23-JAN-2015

BK150279-0 Healthcare-ID, Inc.
1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name: Donor-ID 3.2 integrated with iCASI
App iOS
Cleared Date: 12-NOV-2015

BK160039-0 Healthcare-ID, Inc.
1635 Barclay Blvd.

Buffalo Grove, IL 60089
Trade Name: Donor-ID 3.2 integrated with iCASI
App Android
Cleared Date: 29-JUL-2016

BK170141-0 Helmer Inc.
14400 Bergen Blvd
Noblesville, IN 46060
Trade Name: UltraCW
UltraCW II Automatic Cell Washing
System
Cleared Date: 22-JAN-2018

BK820013-0 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name: Platelet Agitator
Cleared Date: 29-OCT-1982

BK820022-0 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name: Helmer Incubator-Agitator
Cleared Date: 03-JAN-1983

BK840027-0 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name: Helmer Platelet Agitator PF108
Helmer Platelet Agitator PF54
Cleared Date: 16-APR-1985

BK850014-0 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name: PLATELET FLATBED AGITATOR MODEL
PF456
Cleared Date: 30-AUG-1985

BK850015-0 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name: Helmer Incubator Models PC1000
Helmer Incubator Models PC2000
Helmer Incubator Models PC3000
Cleared Date: 20-SEP-1985

BK850018-0 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825

Trade Name: Tube Stripper
Cleared Date: 21-OCT-1985

BK940051-0 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name: Helmer Water Plasma Thawer
Cleared Date: 03-MAR-1995

BK020029-0 Helmer Labs., Inc.
15425 Herriman Boulevard
Noblesville, IN 46060
Trade Name: UltraCW (with Software version 3.13)
Cleared Date: 04-OCT-2002

BK890028-0 Hemagen Diagnostics, Inc.
9033 Red Branch Road
Columbia, MD 21045
Trade Name: Olypmus PK CMV System
Cleared Date: 11-DEC-1989

BK940035-0 Hemagen Diagnostics, Inc.
9033 Red Branch Road
Columbia, MD 21045
Trade Name: Olympus PK TM CMV System & System Controls
Cleared Date: 15-JUL-1996

BK251294-0 Hemanext Inc.
99 Hayden Avenue
Building B, Suite 620
Lexington, MA 02421
Trade Name: Hemanext ONE
Cleared Date: 06-MAR-2026

BK150300-0 Hemasoft Software SL
Antonio Lopez 249, 4 3A
Madrid, SPAIN 28041
Trade Name: e- Delphyn Blood management Software version 7.1.0.0
Cleared Date: 24-OCT-2015

BK200513-0 Hemasoft Software SL
Calle Antonio Lopez, 249 4
, Madrid SPAIN 28041
Trade Name: e-Delphyn LIS Donor - 11.0.0.1
Cleared Date: 09-NOV-2020

BK200515-0 Hemasoft Software SL

Calle Antonio Lopez, 249 4
, Madrid SPAIN 28041
Trade Name: e-Delphyn Donor - 11.0.0.1
Cleared Date: 05-NOV-2020

BK950008-0 Hemasure, Inc.
140 Locke Drive
Marlborough, MA 01752
Trade Name: LeukoNet Pre Storage
Leukodepletion Filteration System
Cleared Date: 28-JUN-1995

BK980014-0 Hemasure, Inc.
140 Locke Drive
Marlborough, MA 01752
Trade Name: HemaSure r|LS Pre-Storage
Leukoreduction Filtration System
for Red Blood Cells
HemaSure r|LS Pre-Storage
Leukoreduction Filtration System
with spike for Red Blood Cells
Cleared Date: 27-MAY-1999

BK070024-0 Hemerus Medical, LLC
5000 Township Parkway
Saint Paul, MN 55110
Trade Name: LEUKOSEP HRC-600-C Leukocyte
Reduction Filtration System for
Red Blood Cells
Cleared Date: 23-AUG-2007

BK080031-0 Hemerus Medical, LLC
5000 Township Parkway
Saint Paul, MN 55110
Trade Name: HEMERUS LEUKOSEP HRC-600-C
Leukocyte Reduction Filtration
System for Red Blood Cells
Cleared Date: 11-SEP-2008

BK261315-0 Hemo Bioscience Inc.
4022 Stirrup Creek Drive
Suite 311
Durham, NC 27703
Trade Name: ELUclear elution kit
Cleared Date: 29-MAY-2026

BK120022-0 Hemo bioscience
801 Capitola Drive, Suite 9
Research Triangle Park
Durham, NC 27713

Trade Name: C3 Control Cells
Cleared Date: 24-OCT-2012

BK140161-0 Hemo bioscience
801 Capitola Drive, Suite 9
Research Triangle Park
Durham, NC 27713
Trade Name: Hemo QC
Cleared Date: 08-SEP-2014

BK160079-0 Hemo bioscience
633 Davis Drive
Suite 100
Morrisville, NC 27560
Trade Name: MQC
Cleared Date: 27-FEB-2017

BK160081-0 Hemo bioscience
633 Davis Drive
Suite 100
Morrisville, NC 27560
Trade Name: MQC-CAT
Cleared Date: 30-MAR-2017

BK060020-0 HemoCue AB
40 Empire Drive
Lake Forest, CA 92630
Trade Name: HemoCue Hb 301 System
Cleared Date: 14-APR-2006

BK060048-0 HemoCue AB
Kuvettgatan 1
Angelholm, SWEDEN SE-262 71
Trade Name: HemoCue Hb 301 System
Cleared Date: 05-OCT-2006

BK000043-0 HemoCue, Incorporated
9229 Cranford Drive
Potomac, MD 20854
Trade Name: HemoCue Low Hemoglobin Analyzing System
Cleared Date: 09-APR-2001

BK030020-0 HemoCue, Incorporated
9229 Cranford Drive
Potomac, MD 20854
Trade Name: Donor Hemoglobin Checker System
Cleared Date: 17-APR-2003

BK030067-0 HemoCue, Incorporated

9229 Cranford Drive
Potomac, MD 20854
Trade Name: HemoCue Donor Hb Checker Control
Cleared Date: 19-DEC-2003

BK040031-0 Hemosystem, S.A.
45, Cours Gouffe
13006 Marseille, FRANCE
Trade Name: Scansytem bacterial detection device
Cleared Date: 23-SEP-2004

BK900024-0 Heraeus Inc.
111A Corporate Blvd, S.
Plainfield, NJ 07080
Trade Name: Cryofuge 6000
Cleared Date: 05-NOV-1992

BK200519-0 Holding Technologies
600-A Royal Commerce Rd
Suite A
Royal Palm Beach, FL 33411
Trade Name: Maximus Blood PRP Kit
Cleared Date: 19-NOV-2020

BK251197-0 HsingChi Medical Ltd.
No. 10, Ln. 82, Shijian St.
Taipei City, Beitou Dist TAIWAN 11276
Trade Name: HsingChi LipoSelector Disposable Fat Collection System (LS-1200)
Cleared Date: 23-DEC-2025

BK220775-0 Hydra Srl
Via Savonarola n 4
, Modena ITALY 41037
Trade Name: Procedure Tray - Lipoaspirate fat harvest and injection kit
Cleared Date: 04-JAN-2023

BK900015-0 I. B. G. Systems Inc.
P.O. Box 5306
Laytonsville, MD 20882
Trade Name: Inverness Blood Grouping System
Cleared Date: 20-SEP-1990

BK920019-0 I. B. G. Systems Inc.
P.O. Box 5306
Laytonsville, MD 20882
Trade Name: Inverness Automated Antibody Screening System

Cleared Date: 26-MAR-1993

BK930025-0 ICU MEDICAL INC
142 TECHNOLOGY DRIVE
IRVINE, CA 92718
Trade Name: Kelsea Clamp Needle Cover & Guide
Cleared Date: 28-OCT-1993

BK110064-0 IT Synergistics, LLC
115 Tree Street
Flowood, MS 39232
Trade Name: DoVac Elite 1.0
Cleared Date: 06-SEP-2012

BK140091-0 IT Synergistics, LLC
115 Tree Street
Flowood, MS 39232
Trade Name: DVac Elite v 2.0
Cleared Date: 09-APR-2014

BK241061-0 IT Synergistics, LLC
115 Tree Street
Flowood, MS 39232
Trade Name: bexWISE API - 1.0
Cleared Date: 25-OCT-2024

BK030087-0 ITL Corporation Pty, Ltd
41-45 Tennant Street
Canberra ACT 2609, AUSTRALIA
Trade Name: ITL SampLok Sampling Kit
Cleared Date: 18-FEB-2004

BK170102-0 ITL Corporation Pty, Ltd
41-45 Tennant Street
Canberra ACT 2609, AUSTRALIA
Trade Name: Samplok Segment Sampler
Cleared Date: 28-NOV-2017

BK980008-0 ITL Corporation, LTD.
22 Molonglo Mall
Fyshwick, Canberra AUSTRALIA 2609
Trade Name: Bloodpack Needle Protector (BNP)
Cleared Date: 07-APR-1998

BK820010-0 Idas America Ltd.
Lockview Plaza
Lockport, NY 14094
Trade Name: Animec
Cleared Date: 14-SEP-1982

BK130046-0 Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: LIFECODES(R) LifeScreen Deluxe (LMX)
Cleared Date: 23-SEP-2013

BK140163-0 Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: PakPlus
Cleared Date: 27-APR-2015

BK160035-0 Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: LIFECODES LifeScreen Deluxe (LMX)
Cleared Date: 21-APR-2016

BK180181-0 Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: DonorScreen-HLA Class I and Class II
Cleared Date: 14-JUN-2018

BK190439-0 Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: MATCH IT! DNA
Cleared Date: 21-JAN-2020

BK210572-0 Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: MATCH IT! Antibody
MATCHI IT! Antibody
Cleared Date: 19-NOV-2021

BK210573-0 Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: LIFECODES LSA Class I
LIFECODES LSA Class II
Cleared Date: 22-NOV-2021

BK210574-0 Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: LIFECODES LSA Class II

Cleared Date: 19-NOV-2021

BK220762-0 Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: MATCH IT! Antibody
Cleared Date: 29-SEP-2022

BK220763-0 Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: LIFECODES LifeScreen XP
Cleared Date: 29-SEP-2022

BK241067-0 Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: MATCH IT! Antibody
MatchX
Cleared Date: 02-JAN-2025

BK130075-0 Immucor Transplant Diagnostics, Inc.
550 West Avenue
Stamford, CT 06902-6352
Trade Name: LIFECODES HLA-A SSO Typing Kit for use with Luminex
LIFECODES HLA-A eRES SSO Typing Kit for use with Luminex
LIFECODES HLA-B SSO Typing Kit for use with Luminex
LIFECODES HLA-B eRES SSO Typing Kit for use with Luminex
LIFECODES HLA-C eRES SSO Typing Kit for use with Luminex
LIFECODES HLA-DQB SSO Typing Kit for use with Luminex
LIFECODES HLA-DRB1 SSO Typing Kit for use with Luminex
LIFECODES HLA-DRB1 eRES SSO Typing Kit for use with Luminex
Cleared Date: 24-DEC-2013

BK150302-0 Immucor Transplant Diagnostics, Inc.
550 West Avenue
Stamford, CT 06902-6352
Trade Name: LIFECODES HLA-DPA1/B1 SSO Typing Kit
LIFECODES HLA-DQAI/B1 SSO Typing Kit
Cleared Date: 11-MAY-2016

BK150343-0 Immucor Transplant Diagnostics, Inc.
550 West Avenue
Stamford, CT 06902-6352
Trade Name: LIFECODES MATCH IT! DNA Software
v1.2
Cleared Date: 11-MAY-2016

BK820019-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Checkcell
Cleared Date: 15-DEC-1982

BK830004-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: 22% Bovine Albumin
Cleared Date: 17-MAR-1983

BK830005-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: 30% Bovine Albumin
Cleared Date: 17-MAR-1983

BK830007-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Low Ionic Strength Solution (LISS)
Cleared Date: 11-MAY-1983

BK830013-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Rh-Hr Control
Cleared Date: 19-JUL-1983

BK830021-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Anti-N Lectin
Cleared Date: 07-NOV-1983

BK830022-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ImmuAdd
Cleared Date: 07-NOV-1983

BK830018-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Anti-A1 Lectin
Cleared Date: 07-NOV-1983

BK840024-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: corQc Test System
Cleared Date: 08-NOV-1984

BK860017-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture P Solid Phase System
Cleared Date: 06-OCT-1986

BK880010-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R (I and II)
Cleared Date: 03-JUN-1988

BK880011-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R (Pooled)
Cleared Date: 03-JUN-1988

BK880014-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Modified Capture-P
Cleared Date: 08-DEC-1988

BK880015-0 Immucor, Inc.

3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-P Platelets Wash & Storage Solution
Cleared Date: 08-DEC-1988

BK880022-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture P Ready Screen Solid Phase Assay
Cleared Date: 03-MAY-1989

BK890012-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture- R Ready- Screen (Pooled)
Cleared Date: 21-JUN-1990

BK890013-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R Ready-Screen (I&II)
Cleared Date: 21-JUN-1990

BK890014-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R Ready-Id
Cleared Date: 21-JUN-1990

BK890022-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Ficin Solution Reagent Set
Cleared Date: 26-JAN-1990

BK920033-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: pHix
Cleared Date: 21-SEP-1993

BK950017-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture S
Cleared Date: 24-OCT-1997

BK950029-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture - CMV
Cleared Date: 22-DEC-1995

BK960016-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Hemaglutination/Dilution Strips
Cleared Date: 04-JUN-1997

BK960017-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Modified Capture-R
Cleared Date: 30-JUN-1998

BK960018-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ABS QC Test System/ABS QC Test System Plus
Cleared Date: 21-JUL-1997

BK960019-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ABS2000
Cleared Date: 30-JUN-1998

BK960020-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture -R Control Cells
Cleared Date: 04-JUN-1997

BK000021-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-S Solid Phase Assay
Cleared Date: 22-JUN-2000

BK000024-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ABS2000, Version 2 software
(2.05.00A and 2.05.00B)
Cleared Date: 03-JUL-2001

BK010002-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ABS2000 (version 1.00.30A SR-1)
Cleared Date: 16-FEB-2001

BK010020-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ABS2000 with Version 2.05.00A
Software
ABS2000 with Version 2.05.00B
Software
ABS2000 with Version1.00.30A SR-2
Software
Cleared Date: 24-SEP-2001

BK020053-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R Ready Indicator Red
Cells
Cleared Date: 27-JAN-2003

BK020054-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R Control Cells
Cleared Date: 27-JAN-2003

BK040010-0 Immucor, Inc.

3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Monoclonal Control
Cleared Date: 23-APR-2004

BK040013-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Galileo version 1.3.6 SP4
Cleared Date: 23-APR-2004

BK040014-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Galileo QC Cell
Cleared Date: 22-APR-2004

BK040023-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: DAT Positive Control Cell
Cleared Date: 23-APR-2004

BK040024-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R Select Solid Phase
System
Cleared Date: 28-APR-2004

BK040057-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Check cell (Weak)
Cleared Date: 06-OCT-2004

BK050050-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-CMV
Galileo Automated Blood Bank
System
Cleared Date: 14-NOV-2005

BK060009-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Galileo Automated Blood Bank System with Capture-S Syphilis Screening Assay
Cleared Date: 11-APR-2006

BK060016-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: corQC Test System
Cleared Date: 09-MAY-2006

BK070013-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Monoclonal Control
Cleared Date: 14-JUN-2007

BK070014-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: DAT Positive Control Cell
Cleared Date: 14-JUN-2007

BK070015-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: WB corQC
Cleared Date: 14-JUN-2007

BK070016-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Galileo Echo Automated Blood Bank System
Cleared Date: 14-JUN-2007

BK070039-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625

Trade Name: corQC Extend
Cleared Date: 28-SEP-2007

BK070040-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Galileo Automated Blood Bank System with assays to perform red blood cell phenotying
Cleared Date: 28-SEP-2007

BK070051-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Immucor's WB corQC
Cleared Date: 16-NOV-2007

BK070054-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Galileo with Reverse ABO Group Assay
Cleared Date: 30-NOV-2007

BK080070-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Automated Blood Bank Analyzer
Cleared Date: 05-FEB-2009

BK090057-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Galileo
Cleared Date: 09-JUL-2010

BK100001-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Galileo Neo
Cleared Date: 29-APR-2010

BK100033-0 Immucor, Inc.
3130 Gateway Drive

P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Galileo Neo
Cleared Date: 23-AUG-2010

BK110050-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Checkcell
Cleared Date: 03-OCT-2011

BK110067-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: FMH RapidScreen
Cleared Date: 22-MAY-2012

BK120016-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ImmuLINK, version 2.0
Cleared Date: 14-JUN-2012

BK120021-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: TPHA Screen
Cleared Date: 24-OCT-2012

BK150333-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ImmuLINK - V.1.7
Cleared Date: 19-NOV-2015

BK170067-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Galileo Neo
Cleared Date: 19-JUL-2017

BK170132-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Galileo Echo

Cleared Date: 27-APR-2018

BK170135-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Echo Lumena
Cleared Date: 27-APR-2018

BK180220-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Galileo Echo
Cleared Date: 17-JUL-2018

BK180243-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: NEO Iris
Neo Iris - Version 3
Cleared Date: 07-NOV-2018

BK180247-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Capture-CMV
Cleared Date: 20-NOV-2018

BK190337-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Galileo NEO
Cleared Date: 19-JUN-2019

BK200474-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: NEO Iris
Cleared Date: 12-JUN-2020

BK200483-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Echo Lumena
Galileo Echo (v.2.0)
Cleared Date: 22-JUN-2020

BK200502-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Galileo NEO

Cleared Date: 13-OCT-2020

BK200542-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Capture-CMV - 0066206, 0066216
Cleared Date: 08-FEB-2021

BK210560-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Galileo NEO
NEO Iris
Cleared Date: 12-APR-2021

BK210562-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Galileo NEO
NEO Iris
Cleared Date: 12-APR-2021

BK210600-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Galileo NEO
NEO Iris
Cleared Date: 03-SEP-2021

BK210601-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: ECHO Lumena
Echo Lumena
Cleared Date: 08-JAN-2025

BK210604-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Complement Control Cells
Cleared Date: 08-JAN-2025

BK210605-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Galileo NEO
Cleared Date: 03-SEP-2021

BK210608-0 Immucor, Inc.
3130 Gateway Drive

Norcross, GA 30071
Trade Name: Galileo Echo
Galileo Neo
Cleared Date: 08-JAN-2025

BK220669-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: NEO Iris
Cleared Date: 26-JUL-2022

BK220670-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Galileo NEO
Cleared Date: 26-JUL-2022

BK220779-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Capture Positive Control Cell
Cleared Date: 10-MAY-2023

BK230806-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ImmuLINK - 3.0
Cleared Date: 25-APR-2023

BK241080-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: ImmuLINK - 3.2
Cleared Date: 06-AUG-2024

BK251256-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: ImmuLINK - 3.3
Cleared Date: 24-OCT-2025

BK110054-0 Immunetics, Inc.
27 Drydock Avenue
Boston, MA 02210-2377
Trade Name: BacTx(R) Bacterial Detection Kit
for Platelets
Cleared Date: 11-JUN-2012

BK130017-0 Immunetics, Inc.

27 Drydock Avenue
Boston, MA 02210-2377
Trade Name: BacTx Reader
BacTx Software
BacTx Bacterial Detection Kit for
Detection of Bacteria in Platelets
Cleared Date: 12-AUG-2013

BK170149-0 Immunetics, Inc.
27 Drydock Avenue
Boston, MA 02210-2377
Trade Name: BacTx Bacterial Detection Kits
Cleared Date: 16-APR-2018

BK910033-0 In-Touch Company
101 N 700 West
Salt Lake City, UT 84954
Trade Name: Alton Dean Model 537 Blood Warmer
Cleared Date: 18-NOV-1992

BK960068-0 Indico, Inc.
Suite 137
6325 103 Street
Edmonton, ALBERTA CANADA T6H 5H6
Trade Name: RadTag
Cleared Date: 30-OCT-1996

BK000008-0 Indico, Inc.
Suite 137
6325 103 Street
Edmonton, ALBERTA CANADA T6H 5H6
Trade Name: RadTag
Cleared Date: 01-MAR-2000

BK950064-0 Informatics
4000 Kruso Way Place
Building 3 Suite 210
Lake Oswego, OR 97035
Trade Name: Lifeline Blood Bank Data
Management System, Release 4.2
Cleared Date: 01-JUL-1998

BK950032-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: Abbott Data Management System,
version 3.0.2
Cleared Date: 18-AUG-1998
Cleared Under Abbott Laboratories

BK950037-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: Components& Distribution
Information System (CDIS)
Cleared Date: 26-AUG-1996

BK950045-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: DONOR MANAGEMENT INFORMATION
SYSTEMS
Cleared Date: 26-AUG-1996

BK980020-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: Plasma Center Management System -
Version 1.0
Cleared Date: 31-JUL-1998

BK980028-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: PCMS - version 1.1
Cleared Date: 04-SEP-1998

BK990016-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: Surround System - 1.0
Cleared Date: 27-AUG-1999

BK990029-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: Plasma Center Management System
(PCMS) Version 1.2
Cleared Date: 13-OCT-1999

BK000016-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: Information Data Management
Surround System - 2.0
Cleared Date: 07-APR-2000

BK990046-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018

Trade Name: Plasma Center Management System
(PCMS) - Version 2.0
Cleared Date: 06-JAN-2000

BK010028-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: IDM Surround System - 3.0
Cleared Date: 05-SEP-2001

BK020038-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: Surround System, Version 3.2
Cleared Date: 08-OCT-2002

BK050014-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: IDM Prelude System, Version 1.1
Cleared Date: 18-JUL-2005

BK070031-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: IDM Symphony System - 2.0
Cleared Date: 13-DEC-2007

BK220700-0 Ingeneron Inc.
8205 EL RIO
HOUSTON, TX 77054
Trade Name: SMARTGRAFT 30 SYSTEM (K141591)
Cleared Date: 24-SEP-2014

BK220701-0 Ingeneron Inc.
8205 EL RIO
HOUSTON, TX 77054
Trade Name: SMARTGRAFT 200 SYSTEM (K141713)
Cleared Date: 28-OCT-2014

BK241079-0 Innoveren Scientific Inc.
151 W 4th St.
Ste. 226
Cincinnati, OH 45202
Trade Name: SkinDisc
SkinDisc Lite
Cleared Date: 28-MAR-2025

BK860042-0 Insta Cool, Inc of North America
11300 Sanders Drive, Suite 14

Rancho Cordova, CA 95742
Trade Name: Insta Cool Model BP2502
Cleared Date: 04-MAR-1987

BK900032-0 Insta Cool, Inc of North America
11300 Sanders Drive, Suite 14
Rancho Cordova, CA 95742
Trade Name: MP III
Cleared Date: 30-MAR-1992

BK910011-0 Insta Cool, Inc of North America
11300 Sanders Drive, Suite 14
Rancho Cordova, CA 95742
Trade Name: MT-200 FROZEN PLASMA THAWER
Cleared Date: 19-DEC-1991

BK940019-0 Insta Cool, Inc of North America
11300 Sanders Drive, Suite 14
Rancho Cordova, CA 95742
Trade Name: Hemopharm PB-500 Pocket Sealer
Cleared Date: 26-SEP-1994

BK850016-0 Integrated Diagnostics, Inc.
1901 Sulphur Spring Road
Baltimore, MD 1227
Trade Name: HLA COMPREHENSIVE TRAY
Cleared Date: 30-DEC-1985

BK870018-0 Integrated Diagnostics, Inc.
1901 Sulphur Spring Road
Baltimore, MD 1227
Trade Name: INDX HLA-DR, DQ Lymphocyte
Phenotyping Tray
Cleared Date: 28-OCT-1987

BK080006-0 IntelliDOT Corporation
13520 Evening Creek Drive North,
Suite 400
San Diego, CA 92128
Trade Name: IntelliDOT Blood Product
Administration
Cleared Date: 13-JUN-2008

BK820001-0 International Business Machines

Princeton, NJ 08540
Trade Name: IBM 2991
Cleared Date: 28-JUN-1982

BK830003-0 International Business Machines

Princeton, NJ 08540
Trade Name: IBM 2991 - Single Unit Leukocytes
from Whole Blood
Cleared Date: 27-MAY-1983

BK830020-0 International Business Machines

Princeton, NJ 08540
Trade Name: Plastic for 2997
Plastic for 2991
Cleared Date: 27-OCT-1983

BK830024-0 International Business Machines

Princeton, NJ 08540
Trade Name: Plastic for 2991
Plastic for 2997
Cleared Date: 09-MAR-1984

BK820020-0 International Equipment Company
300 Second Avenue
Needham Heights, MA 02194
Trade Name: IEC Centra-W Cell Washer
Cleared Date: 05-APR-1983

BK940004-0 International Equipment Company
300 Second Avenue
Needham Heights, MA 02194
Trade Name: Seromax
Cleared Date: 08-APR-1994

BK910018-0 International Specialty Products
1361 Alps Road
Wayne, NJ 07470
Trade Name: RAD-SURE BLOOD IRRADIATION LABEL
Cleared Date: 12-MAR-1992

BK920035-0 International Specialty Products
1361 Alps Rd,
Wayne, NJ 07470
Trade Name: RAD-Sure 2500
Cleared Date: 01-APR-1993

BK120048-0 Intra-Lock International
6560 West Rogers Circle
Boca Raton, FL 33487
Trade Name: Intra-Spin System
Cleared Date: 28-JAN-2013

BK960054-0 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name: Jewett Models BPL13,BPL21,BPL25
Cleared Date: 08-AUG-1996

BK960073-0 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name: Models BBR17, BBR25,BBR37 &BBR55
Cleared Date: 30-OCT-1996

BK960089-0 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name: Jewett Model CT1
Cleared Date: 06-FEB-1997

BK970001-0 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name: Jewett Model CTF-1
Cleared Date: 16-APR-1997

BK970014-0 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name: Jewett Model BBWM3
Cleared Date: 18-JUL-1997

BK970028-0 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name: Jewett Model BPL55
Cleared Date: 15-OCT-1997

BK220716-0 Jointechlabs, Inc.
8 Graystone Court North
Barrington, IL 60010
Trade Name: Jtl-250-01 (K182732)
Cleared Date: 18-NOV-2019

BK860037-0 Jouan, Inc.
Route 8,Box 1202;P.O. Box 2716
Winchester, VA 22601
Trade Name: Model LR5.22 centrifuge
Cleared Date: 15-DEC-1986

BK870001-0 Jouan, Inc.
Route 8,Box 1202;P.O. Box 2716

Winchester, VA 22601
Trade Name: Model GR 4.11 centrifuge
Cleared Date: 20-FEB-1987

BK890027-0 Jouan, Inc.
Route 8,Box 1202;P.O. Box 2716
Winchester, VA 22601
Trade Name: Model KR4-22 Centrifuge
Cleared Date: 02-FEB-1990

BK000003-0 Kawasumi Laboratories, Inc.
1900 K Street
Washington,, DC 20006
Trade Name: Kawasumi Laboratories Phlebotomy Sey
Cleared Date: 20-MAR-2000

BK170113-0 Kawasumi Laboratories, Inc.
Shinagawa Intercity Tower B
2-15-2 Konan
Minato-Ku
Tokyo, JAPAN 108-6109
Trade Name: Kawasumi Laboratories Blood Drawing Kit (BDK) System - BK-64A
Kawasumi Laboratories Blood Drawing Kit (BDK) System
Cleared Date: 27-SEP-2017

BK080057-0 Kaylight Corporation
602 Anacapa
Irvine, CA 92602
Trade Name: My Cells Autologous Platelet Preparation Kit
Cleared Date: 25-SEP-2009

BK200456-0 Kedrion S.p.A.
Loc. Ai Conti
Barga, Lucca ITALY 55051
Trade Name: GeTrap
Cleared Date: 20-APR-2020

BK840005-0 Kontron Blood Bank Systems
9 Plymouth Street
Everett, MA 02149
Trade Name: Kontron Microgroupamatic
Cleared Date: 27-JUN-1984

BK870012-0 Kontron Blood Bank Systems
9 Plymouth Street
Everett, MA 02149

Trade Name: LHS-500 Sampler and Delivery
System
Cleared Date: 02-NOV-1987

BK890008-0 Kontron Blood Bank Systems
9 Plymouth Street
Everett, MA 02149
Trade Name: G-1000
G-2000
G-2000 MK II
Cleared Date: 30-AUG-1989

BK040053-0 Korchek Technologies, LLC
770 Plattsville Road
Trumbull, CT 06611
Trade Name: CareChek Patient Identification
System, CareChek TX - version 1
Cleared Date: 12-AUG-2005

BK030037-0 Kowa Company, Ltd.
c/o Quintiles Consulting
1801 Rockville Pike, Suite 300
Rockville, MD 20852
Trade Name: LD-2000 Leukocyte Counter
Cleared Date: 14-JUN-2004

BK210558-0 LUVO Medical Technologies, Inc.
125 Fleming Dr
, Cambridge CANADA N1T 2B8
Trade Name: World PRP
Cleared Date: 23-JUL-2021

BK100024-0 Lab 21 Healthcare Ltd
184 Cambridge Science Park
Cambridge, Cambridgeshire UNITED KINGDOM CB4 0GA, UK
Trade Name: Lab 21 TPHA OC Kit
Cleared Date: 03-AUG-2010

BK860031-0 Lab-Line Instruments, Inc.
15th and Bloomingdale Avenues
Melrose Park, IL 60160
Trade Name: Hema-Bath
Cleared Date: 02-MAR-1987

BK110055-0 Lattice, Inc.
1751 South Naperville Rd
Suite 100
Wheaton, IL 60189
Trade Name: MediCopia Transfusion - v4.1
Cleared Date: 06-JAN-2012

BK860023-0 Level 1 Technologies, Inc.
160 Weymouth Street
Rockland, MA 02370
Trade Name: Level 1 Fluid Warmer
Cleared Date: 25-SEP-1986

BK920021-0 Level 1 Technologies, Inc.
160 Weymouth Street
Rockland, MA 02370
Trade Name: A/V Rewarming Procedural Kit
Gentilello Technique
Cleared Date: 29-JAN-1993

BK940056-0 Level 1 Technologies, Inc.
160 Weymouth Street
Rockland, MA 02370
Trade Name: Level I Fluid Warmer
Cleared Date: 27-DEC-1994

BK020043-0 Level 1 Technologies, Inc.
160 Weymouth Street
Rockland, MA 02370
Trade Name: level 1 fluid warming system
Cleared Date: 16-JUN-2003

BK230814-0 Life Plasma, Inc.
5438 Perkiomen Ave
Reading, PA 19606
Trade Name: SmartDMS
Cleared Date: 16-APR-2024

BK070038-0 Life Technologies Corporation
9099 North Deerbrook Trail
Brown Deer, WI 53223
Trade Name: AllSet Gold SSP
Cleared Date: 26-SEP-2007
Cleared Under Invitrogen Corporation

BK070041-0 Life Technologies Corporation
9099 North Deerbrook Trail
Brown Deer, WI 53223
Trade Name: DynaChip HLA Antibody Analysis
System
Cleared Date: 30-APR-2008
Cleared Under Invitrogen Corporation

BK070046-0 Life Technologies Corporation
9099 North Deerbrook Trail
Brown Deer, WI 53223

Trade Name: UniMatch Plus Version 4.0
Cleared Date: 27-SEP-2007
Cleared Under Invitrogen Corporation

BK110038-0 Life Technologies Corporation
9099 North Deerbrook Trail
Brown Deer, WI 53223
Trade Name: SeCore HLA Sequencing System
uType Dx HLA Analysis Software v
1.0
Cleared Date: 05-FEB-2013

BK110039-0 Life Technologies Corporation
9099 North Deerbrook Trail
Brown Deer, WI 53223
Trade Name: 3500 Dx/3500 xL Dx Genetic
Analyzer 8 CS2 and 3500 Dx Series
Software
Cleared Date: 05-FEB-2013

BK220709-0 LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876
Trade Name: Revolve Envi 600 Advanced Adipose
System (K163647)
Cleared Date: 25-AUG-2017

BK220721-0 LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876
Trade Name: REVOLVE ENVI 600 Advanced Adipose
System (K193539)
Cleared Date: 28-MAY-2020

BK080017-0 LifeSouth Community Blood Centers Inc.
4039 Newberry Road
Gainesville, FL 32607
Trade Name: Integrated Blood Bank Information
System (IBBIS) Registration Module
- v1.0
Cleared Date: 05-AUG-2008

BK090064-0 LifeSouth Community Blood Centers Inc.
4039 Newberry Road
Gainesville, FL 32607
Trade Name: Integrated Blood Bank Information
System
Cleared Date: 08-DEC-2009

BK130054-0 LifeSouth Community Blood Centers Inc.

4039 Newberry Road
Gainesville, FL 32607
Trade Name: Integrated Blood Bank Information System, version 3.0 (IBBIS)
Cleared Date: 17-JAN-2014

BK160004-0 LifeSouth Community Blood Centers Inc.
4039 Newberry Road
Gainesville, FL 32607
Trade Name: Integrated Blood Bank Information System (IBBIS), Version 4.0
Cleared Date: 29-MAR-2016

BK220703-0 Lipogems International SpA
Viale Bianca Maria 24
Milan, Milano ITALY 20129
Trade Name: The Lipogems System (K142682)
Cleared Date: 22-DEC-2014

BK220707-0 Lipogems International SpA
Viale Bianca Maria 24
Milan, Milano ITALY 20129
Trade Name: Lipogems System (K161636)
Cleared Date: 04-NOV-2016

BK220712-0 Lipogems International SpA
Viale Bianca Maria 24
Milan, Milano ITALY 20129
Trade Name: Lipogems System (K171135)
Cleared Date: 18-MAY-2017

BK220685-0 Lipose Corp
2647 Lin Gate Court
Pleasanton, CA 94566
Trade Name: LIPOSE FAT TRANSFER SYSTEM (K081848)
Cleared Date: 04-DEC-2008

BK830006-0 Liquid Crystal Products, Inc.
724 Algonquin Road
Arlington Heights, IL 60005
Trade Name: HemoTemp II Blood Temperature Indicator
Cleared Date: 04-MAY-1983

BK990013-0 Ljungberg & Kogel
C/O Kamm & Associates
333 Milford Rd.
Deerfield, IL 60015
Trade Name: Biomixer 330 & Biomixer 323

Cleared Date: 07-JUL-1999

BK090010-0 Ljungberg & Kogel
C/O Kamm & Associates
333 Milford Rd.
Deerfield, IL 60015
Trade Name: Biomixer BM330 with XBee (Wireless) Option
Cleared Date: 17-JUL-2009

BK230986-0 MAK-SYSTEM Group Ltd.
1 Bartholomew Lane
, London UNITED KINGDOM EC2N 2AX
Trade Name: ePROGESA - 5.0.3
Cleared Date: 03-NOV-2023

BK251188-0 MAK-SYSTEM Group Ltd.
1 Bartholomew Lane
, London UNITED KINGDOM EC2N 2AX
Trade Name: Patient Health Software (P.H.S) - 2.0
Patient Health Software (P.H.S.) - 11.0.0.0
Cleared Date: 11-JUN-2025

BK180232-0 MAK-SYSTEM SA International Group
10 Avenue de la Grande-Armee
, Paris FRANCE 75017
Trade Name: Patient Health Software (P.H.S) - 2.0
Cleared Date: 18-OCT-2018

BK960050-0 MAK-System
Z.I. Paris Nord II
14, Rue de la Perdrix
95946 Roissy C.D.G. CEDEX, FRANCE B.P. 50035
Trade Name: Progesa
Cleared Date: 10-DEC-1998

BK060035-0 MAK-System
10 Avenue de la Grande Armee
75017 Paris, FRANCE 75017
Trade Name: Patient Health Software - 1.0
Cleared Date: 09-MAY-2007

BK070062-0 MAK-System
10 Avenue de la Grande Armee
75017 Paris, FRANCE 75017
Trade Name: PROGESA - 4.4h
Cleared Date: 26-OCT-2007

BK080002-0 MAK-System
10 Avenue de la Grande Armee
75017 Paris, FRANCE 75017
Trade Name: ePROGESA - 5.0.1
Cleared Date: 13-MAY-2008

BK960029-0 MEDITECH Medical Information Technology, Inc.
MEDITECH Circle
Westwood, MA 02090
Trade Name: MEDITECH
Cleared Date: 19-MAR-1999

BK980046-0 MEDITECH Medical Information Technology, Inc.
MEDITECH Circle
Westwood, MA 02090
Trade Name: Magic Client Server - 5.1
Cleared Date: 08-FEB-2000

BK060029-0 MEDITECH Medical Information Technology, Inc.
MEDITECH Circle
Westwood, MA 02090
Trade Name: MEDITECH MAGIC Blood Bank Software
- 4.9
Cleared Date: 06-FEB-2007

BK080037-0 MEDITECH Medical Information Technology, Inc.
MEDITECH Circle
Westwood, MA 02090
Trade Name: MEDITECH Client Server Blood bank
module 5.6 - v5.6
Cleared Date: 30-OCT-2008

BK080061-0 MEDIWARE INFORMATION SYSTEMS, INC.
11711 West 79th Street
Lenexa, KS 66214
Trade Name: HCLL Donor
Cleared Date: 02-DEC-2008

BK100043-0 MEDIWARE INFORMATION SYSTEMS, INC.
11711 West 79th Street
Lenexa, KS 66214
Trade Name: LifeTrak/Donor - 4.6.0
Cleared Date: 21-OCT-2010

BK100057-0 MEDIWARE INFORMATION SYSTEMS, INC.
11711 West 79th Street
Lenexa, KS 66214
Trade Name: LifeTrak/Lab and Distribution -
4.6.0

Cleared Date: 16-NOV-2010

BK100069-0 MEDIWARE INFORMATION SYSTEMS, INC.
11711 West 79th Street
Lenexa, KS 66214
Trade Name: LifeTrak/Plasma - 1.0.0
Cleared Date: 04-MAR-2011

BK980027-0 MEDSEP Corporation
330 Turnbull Canyon Road
City of Industry, CA 91745
Trade Name: Transfer/Freezing Bag Set
Cleared Date: 26-MAR-1999
Cleared Under MEDSEP Corp.

BK980030-0 MEDSEP Corporation
330 Turnbull Canyon Road
City of Industry, CA 91745
Trade Name: Medsep Freezing bag
Cleared Date: 29-AUG-1998
Cleared Under MEDSEP Corp.

BK980038-0 MEDSEP Corporation
330 Turnbull Canyon Road
City of Industry, CA 91745
Trade Name: Cell Wash/Infusion Bag Set
Cleared Date: 13-JUL-1999
Cleared Under MEDSEP Corp.

BK120026-0 MEDSEP Corporation
1630 Industrial Park Street
Covina, CA 91722
Trade Name: Pall Celeris fPC System
Cleared Date: 29-JUN-2012

BK930021-0 MIGADAS INC
482 Hudson Terrace
Englewood Cliffs, NY 07632
Trade Name: Samplink
Cleared Date: 16-NOV-1993

BK970022-0 MIGADAS INC
482 Hudson Terrace
Englewood Cliffs, NY 07632
Trade Name: samplink
Cleared Date: 18-SEP-1997

BK910007-0 MMED
609 19th Avenue, S.W.
Rochester, MN 55902

Trade Name: MMED Vapor Condensation Blood Warmer
Cleared Date: 16-MAR-1992

BK251212-0 MONARCH LABS, LLC.
17875 SKY PARK CIRCLE
SUITE K
IRVINE, CA 92614
Trade Name: Medical Maggots and maggot confinement dressings
Medical Maggots and maggot confinement dressings (K072438)
Cleared Date: 05-OCT-2007

BK251213-0 MONARCH LABS, LLC.
17875 SKY PARK CIRCLE
SUITE K
IRVINE, CA 92614
Trade Name: Medical Maggots and maggot confinement dressings
Medical Maggots and maggot confinement dressings (K102827)
Cleared Date: 02-NOV-2011

BK910004-0 MPI/Dupaco, Inc.
2620 Temple Heights Drive
Oceanside, CA 92056
Trade Name: Dupaco Blood/Fluid Warming Cuff Set
Cleared Date: 21-FEB-1992

BK231013-0 MUSCULOSKELETAL TRANSPLANT FOUNDATION
125 MAY STREET
EDISON, NJ 08837
Trade Name: LipoGrafter Kit
Cleared Date: 16-MAY-2024

BK030008-0 MacoProductions S.A.S.
3075 Breckinridge Blvd.
Suite 405
Duluth, GA 30096
Trade Name: Leucolab LCG2 Leukoreduction System for Red Blood Cells
Cleared Date: 02-MAY-2003

BK050041-0 MacoProductions S.A.S.
3075 Breckinridge Blvd.
Suite 405
Duluth, GA 30096
Trade Name: Leucolab LCG2 Leukoreduction

System for Red Blood Cells
Cleared Date: 12-OCT-2005

BK080060-0 MacoProductions S.A.S.
3075 Breckinridge Blvd.
Suite 405
Duluth, GA 30096
Trade Name: Leucolab LCG2 Leukoreduction System for AS-1, AS-3, and AS-5 Red Blood Cells
Cleared Date: 14-JAN-2009

BK120071-0 MacoProductions S.A.S.
3075 Breckinridge Blvd.
Suite 405
Duluth, GA 30096
Trade Name: Leucolab LCG2 Leukoreduction Systems for AS-1 Red Blood Cells
Leucolab LCG2 Leukoreduction Systems for AS-1 and AS-3 Red Blood Cells
Leucolab LCG2 Leukoreduction Systems for AS-1, AS-3 and AS-5 Red Blood Cells
Cleared Date: 22-FEB-2013

BK160095-0 MacoProductions S.A.S.
200 chaussee Fernand Forest
, Tourcoing FRANCE 59200
Trade Name: MacoMix HM20 and optional Hemolog 6 Software
Cleared Date: 11-AUG-2017

BK170085-0 MacoProductions S.A.S.
200 chaussee Fernand Forest
, Tourcoing FRANCE 59200
Trade Name: MacoPress Smart (MPS) and DMS Plus
Cleared Date: 09-NOV-2017

BK180306-0 MacoProductions S.A.S.
200 chaussee Fernand Forest
, Tourcoing FRANCE 59200
Trade Name: MacoPress Smart Smarter and DMS Plus
Cleared Date: 24-JAN-2019

BK960075-0 Mallinckrodt Medical, Inc.
675 McDonnell Boulevard
St. Louis, MO 63134
Trade Name: Alton Dean Fluid Warmer, FW-537

Cleared Date: 28-FEB-1997

BK090051-0 McKesson Provider Technologies
5995 Windward Parkway
Alpharetta, GA 30005
Trade Name: Horizon MobileCare Transfusion
Cleared Date: 28-MAY-2010

BK231015-0 MedMira Laboratories Inc.
155 Chain Lake Drive
Suite 1
Halifax, Canada CANADA B3S 1B3
Trade Name: Reveal G4 Rapid HIV-1/2 Antibody Test
Cleared Date: 13-DEC-2023

BK220686-0 Medi-Khan USA INC
655 North Berry St
Brea, CA 92821
Trade Name: LIPOKIT WITH DISPOSABLE 50CC AFT SYRINGE MODEL ZLK-100 (K083455)
Cleared Date: 18-MAY-2009

BK220697-0 Medi-Khan USA INC
655 North Berry St
Brea, CA 92821
Trade Name: LIPOKIT WITH DISPOSABLE 50CC AFT SYRINGE (K121703)
Cleared Date: 07-DEC-2012

BK220687-0 Medical Device Resource Corp
23392 Connecticut St
Hayward, CA 94545
Trade Name: LIPISYSTEMS AQUAVAGE MODELS AV2000 AND AV1200 (K092284)
Cleared Date: 01-SEP-2009

BK180219-0 Medical Information Technology, Inc.
Meditech Circle
Westwood, MA 02090
Trade Name: MEDITECH Expanse Blood Bank
Cleared Date: 12-SEP-2018

BK920031-0 Medical Marketing Consultants
3 Bethesda Metro Center,Suite 750
Bethesda, MD 20814
Trade Name: sHLA-STAT B27 ELISA for HLA-B27 Typing
Cleared Date: 20-AUG-1993

BK140092-0 Medion Grifols Diagnostics AG
Bonnstrasse 9
Duedingen,
Trade Name: DG Gel Extended Control
Cleared Date: 11-APR-2014

BK180280-0 Medion Grifols Diagnostics AG
Bonnstrasse 9
Duedingen,
Trade Name: DG Gel Essential Control
Cleared Date: 17-JAN-2019

BK980034-0 Mediware Information Systems, Inc.
1121 Old Walt Whitman Road
Melville, NY 11747
Trade Name: Hemocare Blood Bank Management
System - Revision 5.2
Cleared Date: 10-DEC-1998

BK010052-0 Mediware Information Systems, Inc.
9000 Harry Hines Blvd
Dallas, TX 75235
Trade Name: LifeTrak Lab - 2.03
Cleared Date: 17-JUN-2002

BK020046-0 Mediware Information Systems, Inc.
900 Oakmont Lane
Westmont, IL 60659
Trade Name: Hemocare LifeLine - Version, 1.0
Cleared Date: 14-FEB-2003

BK030078-0 Mediware Information Systems, Inc.
4545 Fuller Drive, Ste 320
Irving, TX 75038
Trade Name: HCLL - 2.6
Cleared Date: 08-APR-2004

BK040047-0 Mediware Information Systems, Inc.
4545 Fuller Drive, Ste 320
Irving, TX 75038
Trade Name: Instrument Interface Engine - 1.0
Cleared Date: 16-JUL-2004

BK050011-0 Mediware Information Systems, Inc.
4545 Fuller Drive, Ste 320
Irving, TX 75038
Trade Name: HCLL Donor - 1.0
Cleared Date: 10-MAY-2005

BK060019-0 Mediware Information Systems, Inc.

4545 Fuller Drive, Ste 320
Irving, TX 75038
Trade Name: Life Trak / Donor - 3.01
Cleared Date: 21-JUN-2006

BK080049-0 Mediware Information Systems, Inc.
1900 Spring Road, Suite 450
Oak Brook Service Center
Oak Brook, IL 60523
Trade Name: HCLL Transfusion, v3.0
Cleared Date: 22-OCT-2008

BK120036-0 Mediware Information Systems, Inc.
1900 Spring Road, Suite 450
Oak Brook Service Center
Oak Brook, IL 60523
Trade Name: HCLL(TM) Transfusion 2012
Cleared Date: 19-SEP-2012

BK120039-0 Mediware Information Systems, Inc.
1900 Spring Road, Suite 450
Oak Brook Service Center
Oak Brook, IL 60523
Trade Name: LifeTrak(R) 2012
Cleared Date: 05-SEP-2012

BK160066-0 Mediware Information Systems, Inc.
11711 West 79th St
Lenexa, KS 66214
Trade Name: HCLL(TM) Transfusion 2015 R2
Cleared Date: 30-SEP-2016

BK180200-0 Mediware Information Systems, Inc.
11711 West 79th St
Lenexa, KS 66214
Trade Name: LifeTrak 2018
Cleared Date: 03-JUL-2018

BK910019-0 Medsep Corporation
2200 Northern Boulevard
East Hills, NY 11548-1289
Trade Name: Pall BPF4B Leukocyte Removal Blood
Processing Filter wiht Attached
Tubing and Blood Bag
Cleared Date: 16-JAN-1992
Cleared Under Pall Bio Medical

BK920023-0 Medsep Corporation
2200 Northern Boulevard
East Hills, NY 11548-1289

Trade Name: Pall Autostop Leukocyte Removal
Platelet Filter with Tubing
Cleared Date: 26-OCT-1992
Cleared Under Pall Bio Medical

BK940018-0 Medsep Corporation
2200 Northern Boulevard
East Hills, NY 11548-1289
Trade Name: Pall AutoprocessorTM System
Cleared Date: 07-SEP-1994
Cleared Under Pall Bio Medical

BK100058-0 Medsep Corporation
1630 INDUSTRIAL PARK
COVINA, CA 91722
Trade Name: The Pall Celeris fPC System
Cleared Date: 24-FEB-2011

BK010032-0 Medserv, Inc.
71 South Bedford Road
Mount Kisco, NY 10549
Trade Name: Plasmapheresis Data System III -
1.0
Cleared Date: 05-FEB-2002

BK030040-0 Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132
Trade Name: Magellan Autologous Platelet
Separation System
Cleared Date: 03-SEP-2003

BK040068-0 Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132
Trade Name: Magellan Autologous Platelet
Separator System
Cleared Date: 09-NOV-2004

BK940010-0 Mercia Diagnostics Limited
Mercia House, Broadford Park
Shalford, Guildford GU4 8EW, UNITED KINGDOM
Trade Name: CAPTIA TM Syphilis-G
Cleared Date: 03-JAN-1995

BK220706-0 Miami Fat Supply
1510 Max Hooks Rd
Suite F
Groveland, FL 34736
Trade Name: The Red Head Collection Device The

Jordy Connection System (K161372)

Cleared Date: 24-FEB-2017

BK920004-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MGR Model ERB-5-0378
Cleared Date: 12-MAR-1992

BK920013-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Diluent 2
Cleared Date: 29-SEP-1993

BK920014-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Centrifuge
Cleared Date: 29-SEP-1993

BK920016-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Buffered Gel Card
Cleared Date: 29-SEP-1993

BK920030-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Diluent 1
Cleared Date: 29-SEP-1993

BK930030-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Diluent 2 Plus
Cleared Date: 12-JAN-1994

BK940034-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Control Card
Cleared Date: 27-JUL-1994

BK950025-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Incubator
Cleared Date: 08-MAY-1995

BK950026-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Work Table
Cleared Date: 15-MAY-1995

BK950027-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: ID-Pipetor
Cleared Date: 01-JUN-1995

BK950028-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Dispenser (0.5ml and 1.0ml)
Cleared Date: 27-JUN-1995

BK960013-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS-Centrifuge Model NU 9310
Cleared Date: 15-APR-1996

BK980016-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: ID-Tipmaster
Cleared Date: 29-OCT-1998

BK990012-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Reader M
Cleared Date: 19-NOV-1999

BK000018-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Reader SA
Cleared Date: 21-NOV-2000

BK010021-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Incubator II
Cleared Date: 01-OCT-2001

BK030023-0 Micro Typing Systems Inc.

1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: Ortho ProVue, Software Version:
2.10
Cleared Date: 14-MAY-2003

BK090013-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: ORTHO ProVue, version 3.1
Cleared Date: 04-JUN-2009

BK110029-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: Ortho ProVue Analyzer Version 3.1
Patch 1 (V3.1.1)
Cleared Date: 14-JUL-2011

BK150280-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Buffered Gel Card
MTS Monoclonal Control Card
Cleared Date: 14-AUG-2015

BK160061-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS TM Buffered Gel Card
MTS TM Monoclonal Control Card
Cleared Date: 21-OCT-2016

BK190339-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Buffered Gel Card
Cleared Date: 08-JUL-2019

BK190400-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Buffered Gel Card
Cleared Date: 17-DEC-2019

BK251237-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: DAT Control (MTS DAT Card)
Cleared Date: 10-OCT-2025

BK220674-0 MicroAire Surgical Instruments, LLC.
3590 Grand Forks Boulevard
Charlottesville, VA 22911
Trade Name: MicroAire LipoFilter System
Cleared Date: 16-MAR-2022

BK220705-0 MicroAire Surgical Instruments, LLC.
3590 Grand Forks Boulevard
Charlottesville, VA 22911
Trade Name: LipoFilter - Hospital Pack
LipoFilter - Clinic Pack (K150779)
Cleared Date: 22-MAY-2015

BK840023-0 Microdrop, Incorporation
2227 Corinth Ave.
Los Angeles, CA 90064
Trade Name: Leukocyte Typing Serum Trays
Cleared Date: 12-OCT-1984

BK840013-0 Microdrop, Incorporation
2227 Corinth Ave.
Los Angeles, CA 90064
Trade Name: Lambda Cell Tray
Cleared Date: 20-NOV-1984

BK100008-0 Micronics
8463 154th Avenue NE
Redmond, WA 98052
Trade Name: ABORhCard
Cleared Date: 30-APR-2010

BK910034-0 Microwave Medical System
310-312 School St.
Acton, MA 01720
Trade Name: QWIK-1 Bld. and Plasma Warmer
Cleared Date: 29-JUL-1993

BK940003-0 Microwave Medical System
310-312 School St.
Acton, MA 01720
Trade Name: Qwik - 1 TM - 500
Cleared Date: 24-FEB-1994

BK970044-0 Microwave Medical System
310-312 School St.
Acton, MA 01720
Trade Name: ThermoStat 900
Cleared Date: 23-JAN-1998

BK970045-0 Microwave Medical System
310-312 School St.
Acton, MA 01720
Trade Name: ThermoStat 900 Blood & IV Fluid Adm. Set
Cleared Date: 06-MAR-1998

BK860016-0 Miles, Inc.
4th and Parker Streets, P.O. Box 1986
Berkeley, CA 94701-1986
Trade Name: PENTEX MOD-U-CYTE II & VIII
Cleared Date: 17-APR-1987

BK220726-0 Millennium Medical Technologies Inc (DBA Cellmyx)
6352 Corte Del Abeto Ste A
Carlsbad, CA 92011
Trade Name: IntelliFat Disposable Adipose Tissue Harvesting and Transfer Kit, IntelliFat Body On Demand (BOD) Kit (K210528)
Cleared Date: 16-MAR-2022

BK220711-0 Millennium Medical Technologies, INC
460 Saint Michaels Drive
Suite 901
Santa FE, NM 87505
Trade Name: Autoclavable Suction Jar with Luer Lock extension - 250 500 1000 2000 and 3000 ml (K170449)
Autoclavable Suction Jar without Luer Lock extension - 1500 and 2500 ml Sterile 1500 and 2500 (K170449)
Lids with Conical patient connection 6-10 and overflow protection (K170449)
Cleared Date: 31-MAR-2017

BK210653-0 Millipore (UK) Ltd
Fleming Road, Kirkton Campus
, Livingston UNITED KINGDOM EH54 7BN
Trade Name: ORTHO Daily QC, Simulated Whole Blood Quality Control Kit (ORTHO Daily QC Kit)
Cleared Date: 07-JUN-2022

BK090020-0 Miltenyi Biotec, Inc.
120 Presidential Way
Suite 305
Woburn, MA 01801

Trade Name: CryoMACS Freezing Bag
Cleared Date: 13-JAN-2010

BK251174-0 MimiX Biotherapeutics, Ltd
Aarbergstrasse 46, CH-2503
Biel/Bienne, Canton of Bern SWITZERLAND 2503
Trade Name: FastSkin Patch
Cleared Date: 07-NOV-2025

BK030065-0 Mississippi Blood Services, Inc.
1995 Lakeland Drive
Jackson, MS 39216
Trade Name: WebLab Online Laboratory System - 2.0
Cleared Date: 22-DEC-2003

BK040065-0 Misys Healthcare Systems
4801 East Broadway Boulevard
Tucson, AZ 85711
Trade Name: Misys Laboratory Blood Bank and Blood Donor - 6.0.1
Cleared Date: 22-OCT-2004

BK940044-0 Mona Barres
516 Sean Dr.
Metaire, LA 70005
Trade Name: VacMatic Ihs 3-15
Cleared Date: 07-SEP-1994

BK060014-0 Mosum Technology India PVT LTD
55 Northern Blvd, Suite 200
Great Neck, NY 11021
Trade Name: PowerBANK Enterprise Edition - version 1.0
Cleared Date: 30-MAR-2007

BK920024-0 Murex Biologicals, Inc.
1107 I-45 South
Conroe, TX 77301
Trade Name: Murex PEG Potentiator for Antibody Detection
Cleared Date: 01-JUN-1993

BK910016-0 NPBI
Runde ZZ 41, 7881 HM Emmer Compascuum
Emmer-Compascumm, NETHERLANDS
Trade Name: Compomat
Cleared Date: 30-MAR-1992

BK930018-0 NPBI

Runde ZZ 41, 7881 HM Emmer Compascuum
Emmer-Compascumm, NETHERLANDS
Trade Name: Blood Collection Mixer MW 5001
Cleared Date: 24-JUL-1994

BK930020-0 NPBI
Runde ZZ 41, 7881 HM Emmer Compascuum
Emmer-Compascumm, NETHERLANDS
Trade Name: Biotrans Separator
Cleared Date: 27-JUL-1994

BK940061-0 NPBI
Runde ZZ 41, 7881 HM Emmer Compascuum
Emmer-Compascumm, NETHERLANDS
Trade Name: Composeal Mobile and Composeal Universal
Cleared Date: 26-JAN-1995

BK950035-0 NPBI
Runde ZZ 41, 7881 HM Emmer Compascuum
Emmer-Compascumm, NETHERLANDS
Trade Name: Compocool
Cleared Date: 27-SEP-1995

BK960084-0 NPBI
Runde ZZ 41, 7881 HM Emmer Compascuum
Emmer-Compascumm, NETHERLANDS
Trade Name: Gambro Hemofreeze Bag
Cleared Date: 28-MAY-1998

BK940053-0 Nanoentek, Inc.
300 Washington St., STE 416
Newton, MA 02458
Trade Name: Olympus PK System
Cleared Date: 29-NOV-1995
Cleared Under Schiff & Company

BK120015-0 Nanoentek, Inc.
300 Washington St., STE 416
Newton, MA 02458
Trade Name: ADAM-rWBC
Cleared Date: 24-JUL-2012

BK120068-0 Nanoentek, Inc.
300 Washington St., STE 416
Newton, MA 02458
Trade Name: ADAM-rWBC
Cleared Date: 05-DEC-2012

BK180283-0 Nanoentek, Inc.

12f, 5, Digital-Ro 26-Gil Guro-Gu
, Seoul KOREA, SOUTH 152-740
Trade Name: ADAMII CD34 System
Cleared Date: 09-AUG-2019

BK200525-0 Nanoentek, Inc.
851 14, Seohae ro, Paltan myeon
Hwaseong si
, Gyeonggido KOREA, SOUTH 18521
Trade Name: ADAM-rWBC HT System
ADAM-rWBC HT System with ADAM-rWBC
Kit
Cleared Date: 01-DEC-2020

BK210621-0 Nanoentek, Inc.
NanoEntek, Inc.
851-14 Seohae-ro, Paltan-myeon
, Hwaseong-si KOREA, SOUTH 18531
Trade Name: r-Control RBC and PLT
Cleared Date: 28-OCT-2021

BK231031-0 Nanoentek, Inc.
12f, 5, Digital-Ro 26-Gil Guro-Gu
, Seoul KOREA, SOUTH 152-740
Trade Name: ADAMII CD34 System
BD Stem Cell Enumeration Kit
Cleared Date: 05-JUN-2024

BK261351-0 Nanoentek, Inc.
12f, 5, Digital-Ro 26-Gil Guro-Gu
, Seoul KOREA, SOUTH 152-740
Trade Name: ADAMII CD34 System
Cleared Date: 20-JUL-2026

BK950042-0 National Hospital Specialties
104 Johnson Avenue
Hackensack, NJ 07601
Trade Name: Genesis Blood Collection Mixer
Cleared Date: 19-SEP-1995

BK840016-0 Neocyte
199 Weymouth Street
Rockland, MA 02370
Trade Name: NEOPACK System
Cleared Date: 25-JUN-1985

BK050032-0 Neoteric Technology Ltd
205-1099 W. 8th Ave.
Vancouver, British Columbia CANADA V6H 1C3
Trade Name: BloodTrack SafeTx - Version 2.0

Cleared Date: 16-AUG-2005

BK050059-0 Neoteric Technology Ltd
205-1099 W. 8th Ave.
Vancouver, British Columbia CANADA V6H 1C3
Trade Name: BloodTrack Courier - 3.2
Cleared Date: 13-DEC-2005

BK060041-0 Neoteric Technology Ltd
205-1099 W. 8th Ave.
Vancouver, British Columbia CANADA V6H 1C3
Trade Name: BloodTrack - 4.1
Cleared Date: 12-OCT-2006

BK180301-0 Newmarket Biomedical Ltd
Unit 1 Lanwades Business Park
, Kentford UNITED KINGDOM CB8 7PN
Trade Name: PK7400 TP HA Controls
PK7400 TP HA Reagent
Cleared Date: 01-AUG-2019

BK920020-0 Nor-Lake, Inc.
Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name: NSBR211,NSBR482,and NSB763 Blood
Refrigerators
Cleared Date: 19-JAN-1993

BK930002-0 Nor-Lake, Inc.
Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name: NSBR61 (Nor-Lake Scientific Blood
Bank, 6ft Single Door)
Cleared Date: 13-APR-1995

BK930003-0 Nor-Lake, Inc.
Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name: NSBR83 (Nor-Lake Scientific Blood
Bank, 8ft Double Door)
Cleared Date: 13-APR-1995

BK930004-0 Nor-Lake, Inc.
Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name: NSBF211 (Nor-Lake Scientific
Freezers, 21ft Single Door)
Cleared Date: 13-APR-1995

BK930005-0 Nor-Lake, Inc.

Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name: NSBF482 (Nor-Lake Scientific
Plasma Freezers, 48ft Double Door)
Cleared Date: 13-APR-1995

BK930006-0 Nor-Lake, Inc.
Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name: NSBF61 (Nor-Lake Scientific Plasma
Freezer, 6ft Single Door)
Cleared Date: 13-APR-1995

BK900023-0 North American Biologicals, Inc.
16500 N.W. 15th Avenue
Miami, FL 33169
Trade Name: QC-HIV
Cleared Date: 13-NOV-1991

BK910006-0 North American Biologicals, Inc.
16500 N.W. 15th Avenue
Miami, FL 33169
Trade Name: QC-Hepatitis
Cleared Date: 12-MAR-1992

BK920015-0 North American Biologicals, Inc.
16500 N.W. 15th Avenue
Miami, FL 33169
Trade Name: VirocheQC 1
Cleared Date: 20-MAY-1993

BK910028-0 North American Technical Services Corp.
407 E Main St.
Port Jefferson, NY 11777
Trade Name: ASTOTHERM/ASTOTUBE
Cleared Date: 13-JUL-1992

BK110060-0 Novartis Vaccines and Diagnostics, Inc.
4560 Horton St.
Emeryville, CA 94608-2916
Trade Name: PROCLEIX NAT TRACKER Version 3.0
Software
Cleared Date: 01-DEC-2011

BK930023-0 Nu-Quest, Inc.
1031 Meadowview Drive
Webb City, MO 64870
Trade Name: Little Pig Sticker
Cleared Date: 24-FEB-1994

BK830017-0 Nuclear-Medical Laboratories, Division
1800 Hurd Drive
Irving, TX 75061
Trade Name: Hepa-SHure
Cleared Date: 07-OCT-1983

BK080022-0 Olerup SSP AB
Hasselstigen 1
SE 133 33 Saltsjobaden
, SWEDEN
Trade Name: Olerup SSP HLA Typing Kits
Cleared Date: 20-FEB-2009

BK090042-0 Olerup SSP AB
Hasselstigen 1
SE 133 33 Saltsjobaden
, SWEDEN
Trade Name: Olerup SSP HLA Typing Kits
Cleared Date: 11-SEP-2009

BK010040-0 Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: Olympus PK 7200 Automated
Microplate System
Cleared Date: 25-OCT-2001

BK020024-0 Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: Olympus PK7200 Automated
Microplate System
Cleared Date: 08-JUL-2002

BK030009-0 Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: Olympus PK7200 Automated
Microplate System
Cleared Date: 03-MAR-2003

BK040003-0 Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: Olympus PK7200 Automated
Microplate System
Cleared Date: 06-FEB-2004

BK040070-0 Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane

Irving, TX 75063-3104
Trade Name: Tango Automated Blood Bank
Analyzer System
Cleared Date: 22-MAR-2005

BK050076-0 Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: TANGO Automated Blood Bank
Analyzer System (HW Version 02/SW
Version 3.0)
Cleared Date: 16-DEC-2005

BK060024-0 Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: Olympus Bromelin
Olympus PK7300 Automated
Microplate System
Olympus System Control
Cleared Date: 14-MAY-2007

BK060034-0 Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: TANGO Automated Blood Bank
Analyzer System
Cleared Date: 28-AUG-2006

BK090036-0 Olympus America Inc., Diagnostic Systems Division
3500 Corporate Parkway
Center Valley, PA 18034
Trade Name: Olympus PK7300 Automated
Microplate System
Cleared Date: 13-JAN-2010

BK860004-0 Olympus Corporation
4 Nevada Drive
Lake Success, NY 11042
Trade Name: Olympus PK7100
Cleared Date: 14-MAY-1986

BK870025-0 Olympus Corporation
4 Nevada Drive
Lake Success, NY 11042
Trade Name: Olympus PK7100 Automated Blood
Grouping System
Cleared Date: 09-OCT-1987

BK890030-0 Olympus Corporation

4 Nevada Drive
Lake Success, NY 11042
Trade Name: SynthEIA Software System
Cleared Date: 23-JAN-1991

BK930024-0 Olympus Corporation
4 Nevada Drive
Lake Success, NY 11042
Trade Name: Olympus PK7200 Blood Grouping Analyzer
Cleared Date: 26-JAN-1994

BK140093-0 Omrix Biopharmaceuticals Ltd.
PO Box 151, Route22 West
Somerville, NJ 08876-0151
Trade Name: Evicel Application Device
Cleared Date: 03-SEP-2014

BK120014-0 One Lambda, Inc
21001 Kittridge St
Canoga Park, CA 91303
Trade Name: HLA Fusion Software, Version 3.0
Cleared Date: 18-DEC-2012

BK120024-0 One Lambda, Inc
21001 Kittridge St
Canoga Park, CA 91303
Trade Name: LABType (R) SSO DNA Typing Tests for use with LABScanTM 3D
Cleared Date: 20-DEC-2012

BK130009-0 One Lambda, Inc
21001 Kittridge St
Canoga Park, CA 91303
Trade Name: LABScreen for use with LABScan(TM) 3D
Cleared Date: 06-NOV-2013

BK140141-0 One Lambda, Inc
21001 Kittridge St
Canoga Park, CA 91303
Trade Name: LABScreen(R) Multi
Cleared Date: 25-NOV-2014

BK910021-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: Lifesource Flash Bag
Cleared Date: 08-JUN-1992

BK920007-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: Lambda Monoclonal Tray Class I and II
Cleared Date: 28-DEC-1992

BK920009-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: Anti-B27 FITC Conjugated Monoclonal Antibody
Cleared Date: 28-MAR-1997

BK960011-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: Lambda Antigen Tray
Cleared Date: 03-JUL-1997

BK960053-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: Anti-B27 FITC/CD3PE Conjugated Monoclonal Antibody
Cleared Date: 30-OCT-1996

BK960062-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: Micro SSP HLA Class II DNA Typing Kit
Cleared Date: 11-FEB-1998

BK980015-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: FlowPRA
Cleared Date: 23-JUL-1999

BK020055-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LABTYPE SSO Typing Test
Cleared Date: 04-FEB-2003

BK030069-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LABScreen Products for use with

LABScan 100 flow analyzer
Cleared Date: 31-DEC-2003

BK040049-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LabType Visual
Cleared Date: 09-AUG-2004

BK050008-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LABScreen Software
Cleared Date: 08-JUL-2005

BK050070-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: HLA Visual Software version 1.0
Cleared Date: 30-JAN-2006

BK050071-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: HLA Tools Software version 1.0
Cleared Date: 30-JAN-2006

BK070070-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: HLA Fusion Software v 1.0
Cleared Date: 10-MAR-2008

BK080071-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LABScreen Multi
Cleared Date: 10-APR-2009

BK100068-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: HNA Genotyping Trays
Cleared Date: 25-AUG-2011

BK160017-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: HLA Fusion
Cleared Date: 08-MAR-2017

BK160018-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LABTypeTM XR and CWD DNA Typing Test
Cleared Date: 06-MAR-2017

BK170053-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LABType? CWD Class I C Locus Typing Test
LABType? CWD Class I C Locus Typing Test - 20 tests
LABType? XR Class I C Locus Typing Test
LABType? XR Class I C Locus Typing Test - 20 tests
Cleared Date: 05-OCT-2017

BK200546-0 One Lambda, Inc.
22801 Roscoe Blvd
West Hills, CA 92304
Trade Name: LABScreen Multi
Cleared Date: 12-JAN-2021

BK241074-0 One Lambda, Inc.
22801 Roscoe Blvd
West Hills, CA 91304
Trade Name: SeCore CDx HLA Sequencing System
Cleared Date: 01-AUG-2024

BK261357-0 One Lambda, Inc.
22801 Roscoe Blvd
West Hills, CA 91304
Trade Name: SeCore CDx HLA Sequencing System
Cleared Date: 17-JUN-2026

BK190322-0 OrSense Ltd
17 Ha Mefalsim St
Petah Tikva, Kiryat Arie ISRAEL 4951447
Trade Name: NBM-200 Pulse Oximeter and Hemoglobin Monitor
Cleared Date: 09-MAY-2019

BK030036-0 OriGen BioMedical
7000 Burleson Road, Bldg. D
Austin, TX 78744
Trade Name: OriGen Cryostore Freezing Bags

Cleared Date: 01-OCT-2003

BK140116-0 OriGen BioMedical
7000 Burleson Road, Building D
Austin, TX 78744
Trade Name: Origen Transfer Bag
Cleared Date: 19-OCT-2016

BK180278-0 OriGen BioMedical
7000 Burleson Road, Building D
Austin, TX 78744
Trade Name: OriGen Cryostore Multi-Chamber
Freezing Bags
Cleared Date: 21-NOV-2018

BK820003-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO Confidence System
Cleared Date: 10-AUG-1982

BK820006-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: Simwash
Cleared Date: 13-APR-1983

BK830023-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: TYTEM Typing and Detection System
Cleared Date: 08-DEC-1983

BK840017-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO Cell Suspension Tube
Cleared Date: 16-NOV-1984

BK890021-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: Ortho Confidence System
Cleared Date: 23-OCT-1989

BK920034-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: Ortho BioVue System
Cleared Date: 09-MAY-1995

BK960003-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: Ortho Summitt System
Cleared Date: 19-OCT-1998

BK960052-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: Ortho Summit Processor
Cleared Date: 19-OCT-1998

BK990030-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: Ortho Lab with Ortho Lab IC
(Instrument Concentrator)
Cleared Date: 03-APR-2000

BK050044-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: Genetic Systems HIV-1/HIV-2 PLUS O
Ortho Assay Protocol Disk
Cleared Date: 03-NOV-2006

BK050046-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: Genetic Systems HBsAg EIA 3.0
Ortho Assay Protocol Disk
Cleared Date: 13-JAN-2006

BK070028-0 Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101
Trade Name: VITROS Immunodiagnostic Products
Anti-HIV 1+2 Controls
Cleared Date: 10-APR-2008

BK090074-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: Ortho Summit System
Cleared Date: 27-MAY-2009

BK100040-0 Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101

Trade Name: VITROS Immunodiagnostics Products
Anti-HIV 1+2 Controls
Cleared Date: 22-JUL-2010

BK100061-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO VERSEIA Pipetter as part of
the ORTHO Summit System
Cleared Date: 28-OCT-2010

BK110026-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: Ortho Summit System (OSS)
Cleared Date: 28-JUN-2011

BK120006-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO VERSEIA Pipetter as Part of
the ORTHO Summit System (OSS) v
3.0
Cleared Date: 15-MAR-2012

BK130006-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO VERSEIA Integrated
Processor (VIP)
Cleared Date: 23-MAY-2013

BK130032-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO (TM) Workstation
Cleared Date: 09-AUG-2013

BK140207-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO VISION Analyzer
Cleared Date: 14-AUG-2015

BK160058-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO VISION Max Analyzer
Cleared Date: 21-OCT-2016

BK190338-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO VISION Analyzer
Cleared Date: 09-JUL-2019

BK190399-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO VISION Max Analyzer
Cleared Date: 17-DEC-2019

BK200549-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO Optix Reader
Cleared Date: 10-MAR-2021

BK210557-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO VISION Analyzer
ORTHO VISION Max Analyzer
Cleared Date: 13-MAY-2021

BK210564-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO VISION Analyzer
ORTHO VISION Max Analyzer
Cleared Date: 13-MAY-2021

BK220724-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO Optix Reader
Cleared Date: 24-JUN-2022

BK251238-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO VISION Analyzer
ORTHO VISION Max Analyzer
Cleared Date: 10-OCT-2025

BK261331-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO Optix Reader
Cleared Date: 13-MAY-2026

BK241083-0 OrthoAscent
6151 Thornton Avenue
Suite 400
Des Moines, IA 50321
Trade Name: Platelet Rich Plasma (PRP) Device
Cleared Date: 26-SEP-2024

BK040017-0 Orthogen Therapeutics, GmbH
Graf-Adolf-Str. 43
D-40210 Dusseldorf, GERMANY
Trade Name: Osteokin System
Cleared Date: 23-JUN-2004

BK080014-0 Pall Corporation
25 Harbor Park Drive
Port Washington, NY 11050-4630
Trade Name: Pall eBDS
Cleared Date: 13-FEB-2009
Cleared Under Pall Life Sciences

BK150314-0 Pall Corporation
25 Harbor Park Drive
Port Washington, NY 11050-4630
Trade Name: Pall? Briostor? Transfer/Freezing
Bag Set
Cleared Date: 16-JUN-2016

BK120029-0 PatientSafe Solutions
5375 Mira Sorrento Place
Suite 500
San Diego, CA 92121
Trade Name: Patient Touch(TM) Blood Product
Administration System v3.2.1
Cleared Date: 13-NOV-2012

BK820002-0 Pel-Freez Clinical Systems, LLC
PO Box 68
Rogers, AR 72756
Trade Name: Not available from BLT migrated
data.
Cleared Date: 06-OCT-1982

BK820023-0 Pel-Freez Clinical Systems, LLC
PO Box 68
Rogers, AR 72756
Trade Name: Leukocyte Typing Serum (Human)
(Tray Package)
Cleared Date: 12-JAN-1983

BK850004-0 Pel-Freez Clinical Systems, LLC
9099 N. Deerbrook Trail
Brown Deer, WI 53223
Trade Name: Frozen Leukocyte Panel (Human)
Cleared Date: 01-AUG-1985

BK000019-0 Pel-Freez Clinical Systems, LLC
9099 N. Deerbrook Trail
Brown Deer, WI 53223
Trade Name: UniTray SSP HLA Typing Kits
Cleared Date: 29-JAN-2001

BK020068-0 Pel-Freez Clinical Systems, LLC
9099 N. Deerbrook Trail
Brown Deer, WI 53223
Trade Name: Pel Freez HLA High Resolution SSP UniTray
Cleared Date: 14-JAN-2003

BK030003-0 Pel-Freez Clinical Systems, LLC
9099 N. Deerbrook Trail
Brown Deer, WI 53223
Trade Name: UniMatch Plus
Cleared Date: 25-FEB-2003

BK050055-0 Perfusion Partners & Associates, Inc.
6227 Foxfire Lane
Fort Myers, FL 33912
Trade Name: GenesisCS Component Concentrating System
Cleared Date: 13-OCT-2006

BK900018-0 Polar Products, Inc.
2808 Oregon Ct. Bldg K-4
Torrance, CA 90503
Trade Name: Polar Products' Model MTE-58L
Cleared Date: 30-AUG-1990

BK140119-0 ProFibrix BV
Darwinweg 24
Leiden, NETHERLANDS
Trade Name: RaplixaSpray Device
Cleared Date: 30-APR-2015

BK170092-0 Progenika Biopharma, S.A.
Ibaizabal bidea, Edificio 504
Parque Technologico de Bizkaia
Derio, Bizkaia,
Trade Name: ID CORE CONTROL
Cleared Date: 11-OCT-2018

BK010017-0 Psyche Systems Corp
Ten Laurel Avenue
Wellesley, MA 02481
Trade Name: System Blood Bank (SBB) Software - 3.0
Cleared Date: 04-SEP-2001

BK220720-0 Puregraft LLC
420 Stevens Ave
Suite 220
Solana Beach, CA 92075
Trade Name: Dermapose Refresh (K193363)
Cleared Date: 14-APR-2020

BK180188-0 PuriBlood Medical Co. Ltd.
2F., No.11, Gongye E. 9th Rd.
Paoshan Hsiang
, Hsinchu Hsien TAIWAN 30075
Trade Name: Leukocyte Reduction Filter for Red Blood Cells
Leukocyte reduction filter for red blood cells
Cleared Date: 23-NOV-2018

BK840020-0 Queue Systems
22 Airport Industrial Park Rd., Box 1901
Parkersburg, WV 26102
Trade Name: Cryostar
Cleared Date: 23-OCT-1984

BK990005-0 R & D Systems, Inc
614 McKinley Place N.E.
Minneapolis, MN 55413
Trade Name: StatusFlow Pro
Cleared Date: 21-JUN-1999

BK000035-0 R & D Systems, Inc
614 McKinley Place N.E.
Minneapolis, MN 55413
Trade Name: R & D Leuko-Reduced RBC Control
Cleared Date: 13-DEC-2000

BK000036-0 R & D Systems, Inc
614 McKinley Place N.E.
Minneapolis, MN 55413
Trade Name: R & D Leuko-Reduced Plt Control
Cleared Date: 13-DEC-2000

BK040012-0 R & D Systems, Inc

614 McKinley Place N.E.
Minneapolis, MN 55413
Trade Name: R&D Donor Checker Hematology Control
Cleared Date: 05-MAR-2004

BK040063-0 R & D Systems, Inc
614 McKinley Place N.E.
Minneapolis, MN 55413
Trade Name: R & D Plasma Hemoglobin Hematology Control
Cleared Date: 17-SEP-2004

BK910012-0 ROCHE BIOMEDICAL LABORATORIES, INC.
112 ORANGE DRIVE
ELON COLLEGE, NC 27244
Trade Name: HLA CLASS I PHENOTYPING TRAYS
Cleared Date: 06-JAN-1992

BK200543-0 Ranfac Corporation
30 Doherty St
Avon, MA 02322
Trade Name: Ranfac Autologous Platelet Seperator
Cleared Date: 24-FEB-2021

BK220704-0 Ranfac Corporation
30 Doherty St
Avon, MA 02322
Trade Name: Ranfac Fat Aspiration Transfer Syringe (FATS) Procedure Pack
Ranfac Fat Aspiration Transfer Syringe (FATS) Containment Vessel (K150156)
Cleared Date: 19-OCT-2015

BK220708-0 Ranfac Corporation
30 Doherty St
Avon, MA 02322
Trade Name: Ranfac Fat Aspiration Cannula (K162932)
Cleared Date: 19-JAN-2017

BK860034-0 Reagent Laboratory, Inc.
300 East Ottawa Avenue
Louisville, KY 40209
Trade Name: Sodium Chloride 1.3%
Cleared Date: 01-JUN-1987

BK140211-0 Reapplix Aps

Blokken 45
Birkerod, DENMARK
Trade Name: 3C Patch System
Cleared Date: 24-FEB-2016

BK170002-0 Reapplix Aps
Blokken 45
Birkerod, DENMARK
Trade Name: 3C Patch System
Cleared Date: 04-APR-2017

BK200471-0 Reapplix Aps
Blokken 45
Birkerod, DENMARK
Trade Name: 3C Patch System
Cleared Date: 13-JAN-2021

BK230968-0 Reapplix Aps
Blokken 45
Birkerod, DENMARK
Trade Name: 3C Patch System
Cleared Date: 02-APR-2024

BK170095-0 RedDress Ltd
Shkedim Street 11
Pardes Hanna, ISRAEL 370110
Trade Name: RD1 System
Cleared Date: 14-JUN-2018

BK190349-0 RedDress Ltd
Shkedim Street 11
Pardes Hanna, ISRAEL 370110
Trade Name: RD2 System
Cleared Date: 08-NOV-2019

BK200464-0 RedDress Ltd
Shkedim Street 11
Pardes Hanna, ISRAEL 370110
Trade Name: RD2 System
Cleared Date: 20-MAR-2020

BK210570-0 RedDress Ltd
Shkedim Street 11
Pardes Hanna, ISRAEL 370110
Trade Name: RD2 Ver.02 System
Cleared Date: 22-JUN-2021

BK251274-0 Regen Lab USA LLC
95 Green Street
Jersey City, NJ 07302

Trade Name: RegenBMC (RegenKit -THT -BMC)
Cleared Date: 29-MAY-2026

BK090048-0 RegenLab SA
3428 Avenue Marcil
Montreal, Quebec CANADA H4A 2Z3
Trade Name: RegenKit-THT
Cleared Date: 18-MAY-2010
Cleared Under RegenLab SARL

BK110061-0 RegenLab SA
En Budron B2
CH-1052 Le Mont sur Lausanne
, SWITZERLAND
Trade Name: RegenKit-BCT Family Kits
Cleared Date: 08-MAY-2012
Cleared Under RegenLab SARL

BK120057-0 RegenLab SA
3428 Avenue Marcil
Montreal, Quebec CANADA H4A 2Z3
Trade Name: A-CP-Kit Family Kits
Cleared Date: 08-AUG-2013

BK120066-0 RegenLab SA
3428 Avenue Marcil
Montreal, Quebec CANADA H4A 2Z3
Trade Name: RegenKit-ATS-3
RegenKit-BCT-1 Plus
RegenKit-BCT-2 Plus
Cleared Date: 05-FEB-2014

BK210661-0 RegenLab SA
En Budron B2
CH-1052 Le Mont sur Lausanne
, SWITZERLAND
Trade Name: RegenKit-Wound Gel-1
RegenKit-Wound Gel-2
Cleared Date: 08-JUL-2022

BK170128-0 Reichert Inc.
3362 Walden Ave
Suite 100
Depew, NY 14043
Trade Name: TS Meter-DSP
Cleared Date: 19-DEC-2017

BK880029-0 Revco/Lindberg
275 Aiken Road
Asheville, NC 28804

Trade Name: MBF700 Blood Freezer
Cleared Date: 16-JUN-1989

BK890023-0 Revco/Lindberg
275 Aiken Road
Asheville, NC 28804
Trade Name: HLT-20DR-87 Blood Freezer
Cleared Date: 21-SEP-1990

BK890025-0 Revco/Lindberg
275 Aiken Road
Asheville, NC 28804
Trade Name: HLT-50V-4BB Blood Refrigerator
Cleared Date: 02-FEB-1990

BK890026-0 Revco/Lindberg
275 Aiken Road
Asheville, NC 28804
Trade Name: REB3704 Blood Refrigerator
Cleared Date: 02-FEB-1990

BK950054-0 Revco/Lindberg
275 Aiken Road
Asheville, NC 28804
Trade Name: Blood Storage Refrigerator REB2304
Cleared Date: 11-JAN-1996

BK950066-0 Revco/Lindberg
275 Aiken Road
Asheville, NC 28804
Trade Name: Revco HLT 30V-4BB
Cleared Date: 31-JAN-1996

BK890006-0 Rexco
275 Aiken
Asheville, NC 28804
Trade Name: MBF 500 Blood Freezer
Cleared Date: 16-JUN-1989

BK251211-0 Ricarimpex SAS
245 Avenue de Saint Mddard
Eysines, Gironde FRANCE 33320
Trade Name: Medicinal Leeches
Medicinal Leeches (K040187)
Cleared Date: 21-JUN-2004

BK251201-0 Rmedica Co., Ltd.
2-Dong 709-Ho (Gasan-Dong, IT Castle)
98, Gasan Digital 2-Ro
Seoul, Geumcheon-Gu KOREA, SOUTH 08506

Trade Name: DR. PRP-30
DR.PRP-30
Dr.PRP-30
Cleared Date: 22-OCT-2025

BK230839-0 Roche Diagnostics
9115 Hague Rd
Indianapolis, IN 46250
Trade Name: Elecsys Syphilis
Elecsys Syphilis for use on Cobas
Pro Serology Solution
PreciControl Release Syphilis
PreciControl Syphilis
Cleared Date: 31-JUL-2023

BK230840-0 Roche Diagnostics
9115 Hague Rd
Indianapolis, IN 46250
Trade Name: Cytomegalovirus serological
reagents
Elecsys Anti-CMV
Elecsys CMV IgG
PreciControl Anti-CMV
PreciControl CMV IgG
PreciControl Release Anti-CMV
PreciControl Release CMV IgG
Cleared Date: 03-NOV-2023

BK241132-0 Roche Diagnostics
9115 Hague Rd
Indianapolis, IN 46250
Trade Name: cobas pro serology solution
Cleared Date: 06-NOV-2024

BK241148-0 Roche Diagnostics
9115 Hague Rd
Indianapolis, IN 46250
Trade Name: cobas pro serology solution
Cleared Date: 10-JAN-2025

BK251280-0 Roche Diagnostics
9115 Hague Rd
Indianapolis, IN 46250
Trade Name: Elecsys Anti-CMV
Elecsys Syphilis
cobas pro serology solution
Cleared Date: 09-OCT-2025

BK251285-0 Roche Diagnostics
9115 Hague Rd

Indianapolis, IN 46256
Trade Name: Elecsys Syphilis
Cleared Date: 10-DEC-2025

BK261406-0 Roche Diagnostics
9115 Hague Rd
Indianapolis, IN 46256
Trade Name: Elecsys Anti-CMV
Cleared Date: 20-OCT-2026

BK261407-0 Roche Diagnostics
9115 Hague Rd
Indianapolis, IN 46256
Trade Name: Elecsys Syphilis
Cleared Date: 20-OCT-2026

BK020018-0 Roche Molecular Systems, Inc.
4300 Hacienda Drive
P.O. Box 9002
Pleasanton,, CA 94588-0900
Trade Name: Cobas Ampliscreen System
Cleared Date: 26-NOV-2002

BK020025-0 Roche Molecular Systems, Inc.
4300 Hacienda Drive
P.O. Box 9002
Pleasanton,, CA 94588-0900
Trade Name: COBAS AmpliScreen Data Output
Management System (DOMS) - 1.00.04
Cleared Date: 10-DEC-2002

BK140195-0 Roche Molecular Systems, Inc.
4300 Hacienda Drive
P.O. Box 9002
Pleasanton,, CA 94588-0900
Trade Name: Cobas p 680 Instrument
Cobas 8800 System
Cleared Date: 20-OCT-2016

BK140196-0 Roche Molecular Systems, Inc.
4300 Hacienda Drive
P.O. Box 9002
Pleasanton,, CA 94588-0900
Trade Name: cobas p 680 Instrument
cobas 6800 System
Cleared Date: 20-OCT-2016

BK251233-0 Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588

Trade Name: cobas HIV-1/HIV-2 Qualitative
Nucleic acid test for use on the
cobas 5800/6800/8800 systems
Cleared Date: 27-JUN-2025

BK251235-0 Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588
Trade Name: cobas HIV-1 Quantitative nucleic
acid test for use on the cobas
5800/6800/8800 systems
Cleared Date: 01-JUL-2025

BK251286-0 Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588
Trade Name: cobas HIV-1 Quantitative nucleic
acid test for use on the cobas
5800/6800/8800 systems
cobas HIV-1/HIV-2 Qualitative
Nucleic acid test for use on the
cobas 5800/6800/8800 systems
Cleared Date: 21-NOV-2025

BK261349-0 Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588
Trade Name: cobas HIV-1/HIV-2 Qualitative
Control Kit for use on the cobas
5800/6800/8800 systems
cobas HIV-1/HIV-2 Qualitative
Control Kit for use on the cobas
6800/8800 systems
cobas HIV-1/HIV-2 Qualitative
Nucleic acid test for use on the
cobas 5800/6800/8800 systems
cobas NHP Negative Control Kit
for use on the cobas
5800/6800/8800 systems
cobas NHP Negative Control Kit
for use on the cobas 6800/8800
systems
cobas Specimen Pre-Extraction
Reagent (SPER)
Cleared Date: 17-JUN-2026

BK251209-0 Ronald A. Sherman
36 Urey Court
Irvine, CA 92612
Trade Name: CYTORI PUREGRAFT 250/PURE SYSTEM

(K092923)
Medical Maggots
Medical Maggots (K033391)
Cleared Date: 12-JAN-2004

BK110045-0 Rowny Systems, Inc.
7555 Spring Lake Drive
Bethesda, MD 20817-6507
Trade Name: Antigen PLUS - 7.4
Cleared Date: 25-MAY-2012

BK210563-0 Royal Biologics Inc
401 Hackensack Ave
Hackensack, NJ 07601
Trade Name: Royal Maxx Autologous PRP
Concentration System
Cleared Date: 16-APR-2021

BK210632-0 Royal Biologics Inc
401 Hackensack Ave
Hackensack, NJ 07601
Trade Name: Royal MAXX BMC Concentration
System
Royal MAXX PRP Concentration
System
Cleared Date: 11-FEB-2022

BK180204-0 Royal Biologics LLC
190 Columbus Drive
Suite #2A
Jersey City, NJ 07302
Trade Name: Royal MaxxPRP Concentration System
Cleared Date: 12-JUL-2018

BK251232-0 Royal Wound-X, Inc.
401 Hackensack Ave.
Suite 604
Hackensack, NJ 07061
Trade Name: PRF-Matrix System
Cleared Date: 20-FEB-2026

BK990008-0 Rubin & Poor, Inc.
155 Maplewood Avenue #5
Maplewood, NJ 07040
Trade Name: Rubin & Poor Configurable Manual
Blot System - 1.0C
Cleared Date: 29-OCT-1999

BK000030-0 Rubin & Poor, Inc.
155 Maplewood Avenue #5

Maplewood, NJ 07040
Trade Name: Configurable Laboratory Result Manager (CLRM) - 1.0E
Cleared Date: 23-NOV-2001

BK030073-0 Rubin & Poor, Inc.
155 Maplewood Avenue #5
Maplewood, NJ 07040
Trade Name: Configurable Manual Batch Entry - 1.1A
Cleared Date: 14-JAN-2004

BK080028-0 Rubin & Poor, Inc.
155 Maplewood Avenue #5
Maplewood, NJ 07040
Trade Name: Pool results Manager
Cleared Date: 03-SEP-2008

BK050045-0 SCC Soft Computer
34350 U.S. Highway 19 North
Palm Harbor, FL 34684
Trade Name: SoftDonor 4.3 with SoftScape
Cleared Date: 26-OCT-2005

BK060059-0 SCC Soft Computer
34350 U.S. Highway 19 North
Palm Harbor, FL 34684
Trade Name: SoftDonor 4.4 with DMSI - 4.4
Cleared Date: 21-DEC-2006

BK080020-0 SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftBank II - v23.2
Cleared Date: 12-AUG-2008

BK080069-0 SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftDonor 4.5 - 4.5
Cleared Date: 16-JAN-2009

BK090017-0 SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftBank II Version 25 - 25
Cleared Date: 23-JUN-2009

BK090078-0 SCC Soft Computer
5400 Tech Data Drive

Clearwater, FL 33760
Trade Name: SoftID.Tx Version 1.0
Cleared Date: 28-APR-2010

BK100045-0 SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftBank II - 25.1
Cleared Date: 29-JUL-2010

BK140128-0 SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftBank Version 25.5
Cleared Date: 05-AUG-2014

BK200531-0 SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftBank - 25.6.1.0
SoftBank.web - 25.6.1.0
Cleared Date: 18-DEC-2020

BK210607-0 SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftDonor Version 4.5.5.0 -
4.5.5.0
Cleared Date: 14-SEP-2021

BK950057-0 SG Scientific
5745 SW 75th Street
#284
Gainseville, FL 32608
Trade Name: The Saber (Segment Piercing
Device)

Cleared Date: 13-NOV-1995

BK090047-0 SPINESMITH PARTNERS LP
93 Red River
Austin, TX 78701
Trade Name: Fusionary Graft Delivery System
Cleared Date: 10-FEB-2010

BK050052-0 STEMCO Biomedical, Inc.
2810 Meridan Parkway
Suite 148
Durham, NC 27713
Trade Name: Aldecount Progenitor Cell

Enumeration Kit
Cleared Date: 02-DEC-2005

BK130052-0 STRATEC Biomedical UK Limited
1 Barberry Court, Callister Way
Burton upon Trent
,
Trade Name: Procleix NAT Manager Software
(Version 1.1)
Cleared Date: 17-APR-2014

BK160071-0 STRATEC Biomedical UK Limited
Third Ave, Centrum 100
Burton upon Trent
Straffordshire, DE14 2WD UNITED KINGDOM
Trade Name: Aurora Enterprise - Cat. No.
AUR-ENT-001
Cleared Date: 30-OCT-2017

BK160113-0 STRATEC Biomedical UK Limited
98 Main Street
Suite 205
Southington, CT 06489
Trade Name: cobas Synergy Software (Version
1.0)
Cleared Date: 19-APR-2017

BK160124-0 STRATEC Biomedical UK Limited
Third Ave, Centrum 100
Burton upon Trent
Straffordshire, DE14 2WD UNITED KINGDOM
Trade Name: ORTHO CONNECT
Cleared Date: 17-OCT-2017

BK160125-0 STRATEC Biomedical UK Limited
Third Ave, Centrum 100
Burton upon Trent
Straffordshire, DE14 2WD UNITED KINGDOM
Trade Name: Procleix? NAT Manager? v1.2
Software - v1.2
Cleared Date: 25-APR-2017

BK190434-0 STRATEC Biomedical UK Limited
Third Ave, Centrum 100
Burton upon Trent
Straffordshire, DE14 2WD UNITED KINGDOM
Trade Name: ORTHO CONNECT - 3.0
Ortho Connect - 3.0
Cleared Date: 10-MAR-2020

BK231018-0 SUNPHORIA CO., LTD.
12F-1, No. 51, Hengyang Rd.
.
Taipei City, Zhongzheng Dist TAIWAN 10045
Trade Name: AHC Platelet Concentrate Separator
Cleared Date: 10-JAN-2025

BK940017-0 SangStat Medical Corporation
6300 Dumbarton Circle
Freemont, CA 94555
Trade Name: PRA-STAT Elisa/Panel React
Anti-HLA Class I IgG Antibody
Cleared Date: 27-SEP-1994

BK950009-0 SangStat Medical Corporation
6300 Dumbarton Circle
Freemont, CA 94555
Trade Name: CROSS STAT
Cleared Date: 09-MAY-1995

BK970019-0 SangStat Medical Corporation
6300 Dumbarton Circle
Freemont, CA 94555
Cleared Date: 30-JUL-1997

BK970037-0 SangStat Medical Corporation
6300 Dumbarton Circle
Freemont, CA 94555
Trade Name: PRA-STAT Anti-HLA CLASS I IgG
Antibodies/Two Patients per Plate
Format
Cleared Date: 18-NOV-1998

BK940011-0 Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name: Sanguin Medusa 2000
Cleared Date: 29-SEP-1994

BK960065-0 Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name: Sanguin Medusa 2000 - 3.4
Cleared Date: 17-DEC-1998

BK980003-0 Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name: Aurora/Fenestra (version 1.0)
Cleared Date: 29-SEP-1999

BK980039-0 Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name: Medusa 2000 Srimport, Version 1.2
Cleared Date: 11-JUN-1999

BK090061-0 Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name: Sanguin Aurora version 2.0
Cleared Date: 22-DEC-2009

BK100030-0 Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name: Sanguin Liberty SRIMPORT - 3.1
Cleared Date: 08-JUL-2010

BK010042-0 Sarstedt, Inc.
1025 Saint James Church Rd.
Newton, NC 20865
Trade Name: Transwaag KL
Cleared Date: 12-DEC-2001

BK010045-0 Sarstedt, Inc.
1025 Saint James Church Rd.
Newton, NC 20865
Trade Name: Sahara Blood & Plasma Warming
Device
Cleared Date: 21-DEC-2001

BK030006-0 Sarstedt, Inc.
1025 Saint James Church Rd.
Newton, NC 20865
Trade Name: Transwaag Disk 01
Cleared Date: 27-FEB-2003

BK040080-0 Sarstedt, Inc.
1025 Saint James Church Rd.
Newton, NC 20865
Trade Name: Sahara-TSC
Cleared Date: 09-FEB-2005

BK070029-0 Sarstedt, Inc.
1025 Saint James Church Rd.
Newton, NC 20865
Trade Name: S-Monovette ACD-A
Cleared Date: 21-SEP-2007

BK870028-0 Saturn BioTech Corporation
P.O. Box 3823
Littleton, CO 80161
Trade Name: RMED Finger Heme Trap
Cleared Date: 01-FEB-1988

BK940029-0 Scimed Life Systems, Inc.
6655 Wedgewood Rd.
Maple Grove, MN 55311
Trade Name: SCIMED UltraFuse Coron.
Infusion/Guidewire Exchange
Catheter
Cleared Date: 15-MAR-1995

BK870011-0 Seabrook Medical Systems, Inc.
673 Wilmer Aveune
Cincinnati, OH 45226
Trade Name: ECMO-TEMP
Cleared Date: 14-SEP-1987

BK820005-0 Separation Science Corporation
169 Avon Street, P.O. Box 643
Stratford, CT 06497
Trade Name: SEPCOR Cell Line Monitor
Cleared Date: 06-JUL-1982

BK880005-0 Separation Science Corporation
169 Avon Street, P.O. Box 643
Stratford, CT 06497
Trade Name: Blood Bank Saline, Preserved
Cleared Date: 09-JUN-1988

BK050056-0 Separation Technology, Inc.
1096 Rainier Drive
Altamonte Springs, FL 32714-3855
Trade Name: UltraChek Reference Controls -
Product Code GLK
UltraCritTM Hematocrit Measurement
Device - Product Code GKF
Cleared Date: 12-DEC-2005

BK960036-0 Shared Medical Systems
51 Valley Stream Parkway
Malvern, PA 19355
Trade Name: SMS BB Transfusion System
Cleared Date: 12-DEC-1997

BK220688-0 Shippert Medical Technologies Corp.
6248 South Troy Circle
Centennial, CO 80111

Trade Name: TISSU TRANS FILTRON MODELS
3-TT-FILTRON 2000-500 (K092482)
Cleared Date: 04-DEC-2009

BK220692-0 Shippert Medical Technologies Corp.
6248 South Troy Circle
Centennial, CO 80111
Trade Name: TISSU TRANS FILTRON SYRINGE FILL
(K102117)
Cleared Date: 06-AUG-2010

BK990018-0 Shotwell & Carr, Inc.
3535 Firewheel Drive
Suite A
Flower Mound, TX 75028-2628
Trade Name: Hot Shot Fluid Warmer Model 100
Hot Shot Fluid Warmer Model 101
Hot Shot Fluid Warmer Model 102
Hot Shot Fluid Warmer Model 103
Cleared Date: 13-OCT-1999

BK090077-0 Siemens Healthcare Diagnostics, Inc.
P.O. Box 2466
Berkeley, CA 94702
Trade Name: TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 28-DEC-2009
Cleared Under Siemens Healthcare Diagnostics Inc.

BK110007-0 Siemens Healthcare Diagnostics, Inc.
P.O. Box 2466
Berkeley, CA 94702
Trade Name: TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 04-MAR-2011
Cleared Under Siemens Healthcare Diagnostics Inc.

BK120013-0 Siemens Healthcare Diagnostics, Inc.
P.O. Box 2466
Berkeley, CA 94702
Trade Name: TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 27-MAR-2012
Cleared Under Siemens Healthcare Diagnostics Inc.

BK140152-0 Siemens Healthcare Diagnostics, Inc.
511 Benedict Ave
Tarrytown, NY 10591
Trade Name: ADVIA Centaur System (Software
Version 4.0 with SP4

Cleared Date: 08-JUN-2015

BK140153-0 Siemens Healthcare Diagnostics, Inc.
511 Benedict Ave
Tarrytown, NY 10591
Trade Name: ADVIA Centaur XP System (SW v 7.1)
Cleared Date: 08-JUN-2015

BK241075-0 Siemens Healthcare Diagnostics, Inc.
511 Benedict Ave
Tarrytown, NY 10591
Trade Name: Atellica IM HIV Ag/Ab Combo (CHIV)
(10995459)
Cleared Date: 07-NOV-2024

BK960051-0 Siemens Medical Solutions Diagnostics
800 Dwight Way
Berkeley, CA 94701-1986
Trade Name: PPIS - Version 2.0
Cleared Date: 07-AUG-1998
Cleared Under Bayer Corporation

BK990024-0 Siemens Medical Solutions Diagnostics
800 Dwight Way
Berkeley, CA 94701-1986
Trade Name: Plasma Procurement Information
System (PPIS) - 3.0
Cleared Date: 03-NOV-1999
Cleared Under Bayer Corporation

BK990037-0 Siemens Medical Solutions Diagnostics
800 Dwight Way
Berkeley, CA 94701-1986
Trade Name: Plasma Procurement Information
System (PPIS) - Version 4.0
Cleared Date: 17-NOV-1999
Cleared Under Bayer Corporation

BK060015-0 Siemens Medical Solutions Diagnostics
P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name: TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 21-MAR-2006
Cleared Under Bayer HealthCare Diagnostics Division

BK070009-0 Siemens Medical Solutions Diagnostics
P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name: TRUGENE HIV-1 Genotyping Kit and

OpenGene DNA Sequencing System
Cleared Date: 19-MAR-2007

BK080036-0 Siemens Medical Solutions Diagnostics
P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name: TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 20-OCT-2008

BK080073-0 Siemens Medical Solutions Diagnostics
P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name: TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 15-JAN-2009

BK060004-0 Smith & Nephew
1450 Brooks Road
Memphis, TN 38116
Trade Name: Promote Platelet Rich Concentrate
(PRC) Preparation System
Cleared Date: 02-MAY-2006

BK850011-0 Smithkline Beckman Corp.
999 West Valley Road
Wayne, PA 19087
Trade Name: Accugenics (Tray)
Cleared Date: 07-AUG-1985

BK850012-0 Smithkline Beckman Corp.
999 West Valley Road
Wayne, PA 19087
Trade Name: Accugenics (HLA Control Cells)
Cleared Date: 07-AUG-1985

BK080047-0 SofTov Ltd
32 HaShacham Street
Petach Tikva, ISRAEL 49170
Trade Name: AutoFusion - v3.02
Cleared Date: 05-JUN-2009

BK960033-0 Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name: SoftBank II Version 19.1
Cleared Date: 10-JUL-1998

BK000040-0 Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.

Palm Harbor, FL 34684
Trade Name: SoftBank II - 21.2
Cleared Date: 20-APR-2001

BK020006-0 Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name: SoftDonor - 4.1
Cleared Date: 27-FEB-2003

BK020021-0 Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name: SoftBank II - 22
Cleared Date: 11-SEP-2002

BK030018-0 Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name: SoftBank II - 23
Cleared Date: 17-APR-2003

BK040028-0 Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name: SoftBank II with SoftScape - 23
Cleared Date: 07-MAY-2004

BK040048-0 Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name: SoftBank II with Database
Management System Interface (DMSI)
- v23.1
Cleared Date: 23-AUG-2004

BK970032-0 Sorvall, Inc.
31 Pecks Lane
Newtown, CT 06470
Trade Name: RC12BP
Cleared Date: 05-DEC-1997

BK220694-0 Sound Surgical Technologies Inc.
357 McCaslin Boulevard
Louisville, CO 80027
Trade Name: ORIGINS LIPOHARVESTING SYSTEM
(K120328)
Cleared Date: 17-SEP-2012

BK220767-0 StemC Biotechnology Inc

Merkez Mah. Baglar Cad. No:14, B IC Kap
, Kagthane/ Istanbul TURKEY 34330
Trade Name: Centrifuge Container 15 cc
Centrifuge Container 20cc
Lipocube Hybrid I
Lipocube Hybrid II
Lipocube Nano
Cleared Date: 21-DEC-2022

BK251196-0 StemC Biyoteknoloji Anonim Sirketi
StemC Biyoteknoloji Anonim Sirketi
B:2 Blok I Kapi No:27 Kagithane
Istanbul, Istanbul TURKEY 34406
Trade Name: Exocube Set
Cleared Date: 28-AUG-2025

BK030064-0 Stemco Biomedical, Incorporated
2810 Meridian Parkway
Suite 148
Durham, NC 27713
Trade Name: Aldecount Progenitor Cell
Enumeration Kit
Cleared Date: 31-DEC-2003

BK040075-0 Stemco Biomedical, Incorporated
2810 Meridian Parkway
Suite 148
Durham, NC 27713
Trade Name: Aldecount Progenitor Cell
Enumeration Kit
Cleared Date: 06-JAN-2005

BK220718-0 Stemics S.A.S
2 Rue Professeur Paul Milleret
, Besancon FRANCE 25000
Trade Name: KTA Adipose Treatment Kit
(K190386)
Cleared Date: 10-OCT-2019

BK860030-0 Stephens Scientific
7 Astro Place Box 1116
Denville, NJ 07834
Trade Name: Stephens Scientific Certified
Blood Bank Saline
Cleared Date: 16-DEC-1986

BK870015-0 Stephens Scientific
7 Astro Place Box 1116
Denville, NJ 07834
Trade Name: Certified Blood Bank Saline,

Preserved
Cleared Date: 02-NOV-1987

BK870016-0 Stephens Scientific
7 Astro Place Box 1116
Denville, NJ 07834
Trade Name: Certified Saline, Preserved
Cleared Date: 02-NOV-1987

BK880013-0 Stericon Inc.
2315 Gardner Road.
Broadview, IL 60153
Trade Name: RCM-10 Pediatric Sized Freezing Bag
Cleared Date: 09-NOV-1988

BK920022-0 Stericon Inc.
2315 Gardner Road.
Broadview, IL 60153
Trade Name: MB-30 Empty Plastic Containers
Cleared Date: 03-JUN-1993

BK200477-0 Suneva Medical, Inc.
5870 Pacific Center Blvd
San Diego, CA 92121
Trade Name: Amplifine Gel Separator Tubes
Suneva HD PRP Platelet Preparation System
Cleared Date: 30-SEP-2020

BK990002-0 Sunquest Information Systems, Inc.
4801 Broadway Boulevard
Tucson, AZ 85711
Trade Name: Flexilab - 5.2
Cleared Date: 16-AUG-1999

BK990034-0 Sunquest Information Systems, Inc.
4801 Broadway Boulevard
Tucson, AZ 85711
Trade Name: FlexiLab Blood Bank and Blood Donor System - Version 5.2
Cleared Date: 17-NOV-1999

BK080021-0 Sunquest Information Systems, Inc.
250 S. Williams Blvd.
Tucson, AZ 85711
Trade Name: Sunquest Transfusion Manager - v1.0
Cleared Date: 14-SEP-2017

BK080042-0 Sunquest Information Systems, Inc.
250 S. Williams Blvd.
Tucson, AZ 85711
Trade Name: Sunquest Blood Bank Donor - 6.4
Cleared Date: 03-MAR-2009

BK140124-0 Sunquest Information Systems, Inc.
250 S. Williams Blvd.
Tucson, AZ 85711
Trade Name: Sunquest Transfusion Manager
version 2.0
Cleared Date: 18-JUN-2014

BK160005-0 Sunquest Information Systems, Inc.
250 S. Williams Blvd.
Tucson, AZ 85711
Trade Name: Sunquest Blood Bank and Blood
Donor - Version 8.0
Cleared Date: 25-MAR-2016

BK210556-0 Sunquest Information Systems, Inc.
3330 East Sunrise Dr
Tucson, AZ 85718
Trade Name: Sunquest Transfusion Manager - 3.0
Sunquest Transfusion Manager
Version 3.0
Cleared Date: 16-APR-2021

BK120061-0 SynGen, Inc
2125 19th Street, Suite 120
Sacramento, CA 95818
Trade Name: SynGenX-1000
Cleared Date: 12-JUL-2013

BK251268-0 Synova Life Sciences, Inc.
1927 Paseo Rancho Castilla
Los Angeles, CA 90032
Trade Name: Synova WAVE Adipose Processing
System
Cleared Date: 17-NOV-2025

BK220723-0 Syntr Health Technologies, Inc.
5270 California Ave
Irvine, CA 92617
Trade Name: Syntrfuge System (K203800)
Cleared Date: 02-JUL-2021

BK120067-0 SysLogic, Inc.
375 Bishops Way, Suite 105
Brookfield, WI 53005

Trade Name: iTrace for Blood Centers -
1.0.924.0
Cleared Date: 14-SEP-2017

BK960034-0 SysTec Computer Associates, Inc.
738 Smithtown Bypass
Smithtown, NY 11787
Trade Name: Lifetec Comm. Blood Center
System-Rev 2.10
Cleared Date: 28-JUL-1998

BK990003-0 SysTec Computer Associates, Inc.
28 North Country Road
Mt. Sinai, NY 11766
Trade Name: LifeTec - 2.20
Cleared Date: 30-JUL-1999

BK040026-0 SysTec Computer Associates, Inc.
28 North Country Road
Mt. Sinai, NY 11766
Trade Name: LifeTec Donor Verification and
Collection System (DOVAC) - 1.00
Cleared Date: 21-OCT-2004

BK060032-0 SysTec Computer Associates, Inc.
28 North Country Road
Mt. Sinai, NY 11766
Trade Name: LifeTec Elite - 1.0
Cleared Date: 15-AUG-2006

BK210559-0 Sysmex America, Inc.
577 Aptakisic Rd
Lincolnshire, IL 60069
Trade Name: Sysmex XN-10 Automated Hematology
Analyzer
Cleared Date: 27-MAY-2021

BK210631-0 Sysmex America, Inc.
577 Aptakisic Rd
Lincolnshire, IL 60069
Trade Name: Sysmex XN-10 Automated Hematology
Analyzer
Cleared Date: 23-MAY-2022

BK120076-0 TERUMO BCT
10811 W. Collins Ave
Lakewood, CO 80215-4440
Trade Name: Spectra Optia Apheresis System
Cleared Date: 25-FEB-2013

BK130031-0 TERUMO BCT
10811 W. Collins Ave
Lakewood, CO 80215-4440
Trade Name: Spectra Optia Apheresis System
Cleared Date: 25-JUL-2013

BK130065-0 TERUMO BCT
10811 W. Collins Ave
Lakewood, CO 80215-4440
Trade Name: Spectra Optia Apheresis System
Cleared Date: 16-JAN-2014

BK130080-0 TERUMO BCT
10811 W. Collins Ave
Lakewood, CO 80215-4440
Trade Name: Trima Accel System, Version 6.2
Cleared Date: 19-MAR-2014

BK140151-0 TERUMO BCT
10811 W. Collins Ave
Lakewood, CO 80215-4440
Trade Name: Spectra Optia Apheresis System
Cleared Date: 13-AUG-2014

BK150251-0 TERUMO BCT
10811 W. Collins Ave
Lakewood, CO 80215-4440
Trade Name: Spectra Optia Apheresis System
Cleared Date: 16-JUL-2015

BK160116-0 TERUMO BCT
10811 W. Collins Ave
Lakewood, CO 80215-4440
Trade Name: Trima Accel Automated Blood
Collection System
Cleared Date: 23-DEC-2016

BK230838-0 TERUMO BCT
10810 W. Collins Ave
Lakewood, CO 80215
Trade Name: IMUGARD WB PLT Platelet Pooling
Set
Reveos Equipment
Reveos SELECT Disposable Set
Reveos Automated Whole Blood
Processing System
Cleared Date: 27-JUL-2023

BK231035-0 TERUMO BCT
10810 W. Collins Ave

Lakewood, CO 80215
Trade Name: Rika Plasma Donation System - 2.1
Cleared Date: 07-MAR-2024

BK120012-0 TERUMO Corporation
10811 W. Collins Avenue
Lakewood, CO 80215
Trade Name: Spectra Optia Apheresis System
Cleared Date: 09-JUL-2012

BK120017-0 TERUMO Corporation
10811 W. Collins Avenue
Lakewood, CO 80215
Trade Name: Trima Accel Automated Blood
Component Collection System
Cleared Date: 31-MAY-2012

BK120040-0 TERUMO Corporation
10811 W. Collins Avenue
Lakewood, CO 80215
Trade Name: Trima Accel System
Cleared Date: 03-OCT-2012

BK120049-0 TERUMO Corporation
10811 W. Collins Avenue
Lakewood, CO 80215
Trade Name: Trima Accel System
Cleared Date: 17-DEC-2012

BK220695-0 THE GID GROUP INC.
901 Front Street
Louisville, CO 80027
Trade Name: GID 700 (K120902)
Cleared Date: 15-AUG-2012

BK220702-0 THIEBAUD SAS
2 impasse des primbois
Margencel, Haute-Savoie FRANCE 74200
Trade Name: ST'RIM (K142073)
Cleared Date: 29-APR-2015

BK220750-0 THIEBAUD SAS
2 impasse des primbois
Margencel, Haute-Savoie FRANCE 74200
Trade Name: macro st rim
macro st rim
mini st rim
mini st rim
nano st rim
nano st rim

st rim
Cleared Date: 26-AUG-2022

BK970012-0 Tahoe Chemical R & D
2230 Damon Road
Carson City, NV 89701
Trade Name: Nover Trip Scale Alarm
Cleared Date: 14-JUL-1997

BK040062-0 Talisman Ltd.
421 Church Street NE. Suite F
Vienna, VA 22180
Trade Name: Quality Donor System 2004 - 2.0
Cleared Date: 18-OCT-2004

BK060031-0 Talisman Ltd.
421 Church Street NE. Suite F
Vienna, VA 22180
Trade Name: Talisman Phlebotomy System Release
1.0
Cleared Date: 27-JUL-2006

BK070020-0 Talisman Ltd.
421 Church Street NE. Suite F
Vienna, VA 22180
Trade Name: Quality Donor System - v2.1
Cleared Date: 16-JUL-2007

BK980021-0 Talon Medical, Ltd.
18160 Highway 281 N
Suite 108
San Antonio, TX 78232
Trade Name: Cord-X System
Cleared Date: 20-JAN-1999

BK251207-0 Techno-Path Manufacturing Ltd.
Fort Henry Business Park
Ballina
Co. Tipperary, Munster IRELAND V94 FF1P
Trade Name: Multichem ID-HIV p24
(09915494190)
Multichem ID-HIV p24 (SR1111U)
Multichem ID-HIV p24 Mini Kit
(SR1111MU)
Cleared Date: 02-JAN-2026

BK050003-0 Tepnel Lifecodes Corporation
550 West Avenue
Stamford, CT 06902
Trade Name: LIFECODES HLA-A Typing Kit for use

with Luminex 100, LIFECODES HLA-B Typing Kit for use with Luminex 100, HLA-C Typing Kit for use with Luminex 100
LIFECODES HLA-DQB Typing Kit for use with Luminex 100 and
LIFECODES HLA-DRB Typing Kit for use with Luminex 100
Cleared Date: 18-JUL-2005

BK080050-0 Tepnel Lifecodes Corporation
550 West Avenue
Stamford, CT 06902
Trade Name: LIFECODES HLA Typing Kits (HLA-A, B, C, DQB, DRB, DRB1) for use with Luminex
Cleared Date: 13-NOV-2008

BK090018-0 Tepnel Lifecodes Corporation
550 West Avenue
Stamford, CT 06902
Trade Name: LIFECODES Evolution Software, version 1.0
Cleared Date: 04-JUN-2009

BK010006-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Automated Blood Component Collection System
Cleared Date: 27-FEB-2002
Cleared Under Gambro BCT, Inc

BK010037-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Platelet collection sets for the COBE Spectra Apheresis System and the Trima Automated Blood Component Collection System.
Cleared Date: 24-SEP-2003
Cleared Under Gambro BCT, Inc

BK010046-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Automated Blood Collection System (Single Stage)
Cleared Date: 18-SEP-2002
Cleared Under Gambro BCT, Inc

BK010050-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Automated Blood Collection System
Cleared Date: 18-SEP-2002
Cleared Under Gambro BCT, Inc

BK020015-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System, Independent Solution
Cleared Date: 15-JUL-2002
Cleared Under Gambro BCT, Inc

BK020041-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: COBE Spectra Apheresis System/Blood component disposable collection sets for apheresis
Cleared Date: 23-APR-2003
Cleared Under Gambro BCT, Inc

BK030021-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System - 2.1
Cleared Date: 01-MAY-2003
Cleared Under Gambro BCT, Inc

BK030083-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel
Cleared Date: 14-JAN-2004
Cleared Under Gambro BCT, Inc

BK040069-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Automated Blood Component Collection System - Blood Component Sampling Accessory
Cleared Date: 28-OCT-2004
Cleared Under Gambro BCT, Inc

BK040086-0 Terumo BCT, Inc

10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: COBE Spectra Apheresis System &
Trima Automated Blood Component
Collection System
Cleared Date: 15-MAR-2005
Cleared Under Gambro BCT, Inc

BK070001-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System - 3.0
Cleared Date: 27-JUN-2007
Cleared Under Gambro BCT, Inc

BK070066-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System, Version
3.0 with Medical Review Module
Cleared Date: 13-DEC-2007
Cleared Under Gambro BCT, Inc

BK080010-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: The Atreus Whole Blood Processing
System
Cleared Date: 27-JUN-2008
Cleared Under Gambro BCT, Inc

BK080029-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel Automated Blood
Component Collection System
Cleared Date: 18-MAY-2010
Cleared Under Gambro BCT, Inc

BK140104-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System Version
3.2
Cleared Date: 01-APR-2014

BK140158-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel System

Version 6.4
Cleared Date: 29-AUG-2014

BK140180-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Model 81000
Trima Accel System Mobile Pro
Package
Cleared Date: 05-NOV-2014

BK140191-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Spectra Optia Apheresis System
Cleared Date: 09-MAR-2015

BK150228-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System - 4.0
Cleared Date: 22-SEP-2015

BK150269-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel system
Cleared Date: 06-AUG-2015

BK150321-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel System
Cleared Date: 16-OCT-2015

BK160082-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: T-Cuff
Cleared Date: 19-AUG-2016

BK160108-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: TSCD-II Sterile Tubing Welder with
or without Trucise Total System
(TM), Model ME-SC203A
Cleared Date: 23-NOV-2016

BK170059-0 Terumo BCT, Inc

10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel (R) Blood Collection System
Cleared Date: 07-JUL-2017

BK170098-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: TSCD-II Sterile Tubing Welder with or without Trucise Total System (TM)
Cleared Date: 29-SEP-2017

BK170157-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: Trima Accel(R) Blood Collection System
Cleared Date: 06-APR-2018

BK180231-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: Trima Accel(R) Blood Collection System
Trima Accel Automated Blood Collection System
Cleared Date: 17-AUG-2018

BK180258-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: Vista Information System
Cleared Date: 18-JAN-2019

BK190332-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: Trima Accel Blood Collection System
Cleared Date: 22-MAY-2019

BK190333-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: TOMEs - 7
Cleared Date: 03-DEC-2019

BK210591-0 Terumo BCT, Inc

10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: Harvest PRP Separation System
Harvest PRP Separation System with ACDA (30 mL)
Harvest PRP Separation System with LP-10
SmartPrep2 System
Cleared Date: 11-FEB-2022

BK210635-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: Rika Plasma Bottle
Rika Plasma Donation System
Rika Plasma Separation Set
Cleared Date: 07-MAR-2022

BK210658-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: IMUGARD WB PLT Platelet Pooling Set
Cleared Date: 26-AUG-2022

BK230843-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: IMUGARD WB PLT Platelet Pooling Set
Reveos Automated Whole Blood Processing System
Cleared Date: 27-JUL-2023

BK241097-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Rika Plasma Donation System (42000)
Cleared Date: 05-NOV-2024

BK820015-0 Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name: Plasmaflex Pooling Bottle
Cleared Date: 12-NOV-1982

BK850017-0 Terumo Corporation
2805 East Ana Street
Compton, CA 90221

Trade Name: Plasmaflex Bottles
Cleared Date: 04-NOV-1985

BK860012-0 Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name: Imugard Leukocyte Filter
Cleared Date: 16-MAY-1990

BK890005-0 Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name: Stericell Cell Processor
Cleared Date: 10-OCT-1989

BK890017-0 Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name: Teruflex Transfer Bag
Cleared Date: 18-JUL-1990

BK890032-0 Terumo Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: Immugard-E- Leukocyte Removal From
Red Blood Cells
Cleared Date: 18-JUL-1990

BK900028-0 Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name: Terufusion Plasma Transfer Set
Cleared Date: 22-OCT-1990

BK920040-0 Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name: Venoject II Holder
Cleared Date: 20-MAY-1993

BK950039-0 Terumo Corporation
2100 Cottontail Lane
Somerset, NJ 08873
Trade Name: Teruflex B-600 Terumo Blood Bag
without anticoagulant
Cleared Date: 25-AUG-1995

BK950058-0 Terumo Corporation
2100 Cottontail Lane
Somerset, NJ 08873

Trade Name: Terumo Sampling Site Coupler
Cleared Date: 13-NOV-1995

BK860041-0 Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: SCD 312
Cleared Date: 01-JUN-1987

BK970008-0 Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: Terumo Sterile Tubing Welder
SC-201A (TSCD)
Cleared Date: 28-MAY-1998

BK970011-0 Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: Terumo Phlebotomy Needle Cap
Holder
Cleared Date: 19-JUN-1997

BK000045-0 Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: Imugard III-PL
Cleared Date: 28-SEP-2001

BK020033-0 Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: Imugard III-PL Leukocyte reduction
filter
Cleared Date: 22-MAY-2003

BK040082-0 Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: TSCD-II Terumo Sterile Tubing
Welder
Cleared Date: 05-APR-2005

BK070018-0 Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: TRUCISE Total System
Cleared Date: 22-JAN-2008

BK110071-0 Terumo Medical Corporation

950 Elkton Blvd
Elkton, MD 21921
Trade Name: TSCD (R) II Sterile Tubing Welder
& Trucise Total System (R)
Cleared Date: 12-SEP-2012

BK980002-0 Teva Medical LTD
482 Hudson Terrace
Englewood Cliffs, NJ 07632
Trade Name: SegMed
Cleared Date: 02-MAR-1998

BK060060-0 Texas BioGene, Inc.
635 Presidential Drive
Richardson, TX 75081
Trade Name: Morgan HLA SSP ABDR Typing Kit
Cleared Date: 22-MAR-2007

BK080039-0 Texas BioGene, Inc.
635 Presidential Drive
Richardson, TX 75081
Trade Name: Morgan HLA SSP ABCDRDQ Typing Kit
Cleared Date: 22-APR-2009

BK050058-0 The Surgical Company International
Terminalweg 19a
Amersfoort, NETHERLANDS 3821 AJ
Trade Name: Fluido Blood and Fluid Warmer
System
Cleared Date: 05-MAY-2006

BK070055-0 The Surgical Company International
Terminalweg 19a
Amersfoort, NETHERLANDS 3821 AJ
Trade Name: Fluido Air Guard
Fluido Compressor
Fluido IV-Pole
Fluido Pressure Chamber
Cleared Date: 15-JAN-2008

BK950067-0 Thermal Transfer Technology
681 Main Street
Placerville, CA 95667
Trade Name: Thermal Ware
Cleared Date: 14-FEB-1996

BK160044-0 Thermo Electron LED GmbH (a subsidiary of Thermo Fisher Scientific Inc.)
Am Kalkberg
Osterode am Harz,

Trade Name: Thermo Scientific CW3 Cell Washer
Cleared Date: 07-OCT-2016

BK180198-0 ThermoGenesis Corp
2700 Citrus Rd
Ranco Cordova, CA 75741
Trade Name: AXP II AutoXpress Platform
Cleared Date: 14-NOV-2018

BK960072-0 Thermogenesis
3146 Gold Camp Drive
Suite 206
Rancho Cordova, CA 95670-6022
Trade Name: CryoSeal System
Cleared Date: 12-FEB-1999

BK960074-0 Thermogenesis
3146 Gold Camp Drive
Suite 206
Rancho Cordova, CA 95670-6022
Trade Name: HemoMatic Blood Collection Monitor
Cleared Date: 03-APR-1997

BK030011-0 Thermogenesis
3146 Gold Camp Drive
Suite 206
Rancho Cordova, CA 95670-6022
Trade Name: ThermoGenesis Thawer
Cleared Date: 10-JUN-2003

BK070006-0 Thermogenesis
2711 Citrus Road
Rancho Cordova, CA 95742
Trade Name: AXP AutoXpress Platform
Cleared Date: 05-OCT-2007

BK100066-0 Thermogenesis
2711 Citrus Road
Rancho Cordova, CA 95742
Trade Name: ThermoGenesis Res-Q60 PRP Device
Cleared Date: 27-MAY-2011

BK900017-0 Thermopol Inc.
2481 B Delta Ln,
Elk Grove Village, IL 60007
Trade Name: Solid State Portable Refrigerator
Cleared Date: 30-AUG-1990

BK940038-0 Thomson & Neilsen, Ltd.
1050 Baxter Road

Ottawa, Ontario, Canada, CANADA
Trade Name: Blood Irradiator Dosimetry System TN-ID-50
Cleared Date: 18-MAY-2026

BK190433-0 Tiger Aesthetics Medical, LLC
9779 S. Franklin Dr.
Suite #300
Franklin, WI 53132
Trade Name: AuraGen 1-2-3 with AuraClens Suction Lipoplasty System (A123+ AuraClens)
Cleared Date: 13-MAR-2020

BK150289-0 Timestrip UK Ltd.
22 Friars Street
Sudbury
, Suffolk UNITED KINGDOM CO102AA
Trade Name: Timestrip(R) Blood Temp 10 (BT10)
Cleared Date: 14-DEC-2015

BK190363-0 Timestrip UK Ltd.
22 Friars Street
Sudbury
, Suffolk UNITED KINGDOM CO102AA
Trade Name: Timestrip Blood Temp 10
Cleared Date: 22-JUL-2019

BK850007-0 Trayser, Inc.
P.O. Box 83
Cabin John, MD 20818
Trade Name: Trayser DR/DQ Typing Tray Kit
Cleared Date: 25-APR-1985

BK030066-0 Tyco Healthcare
15 Hampshire Street
Mansfield, MA 02048
Trade Name: Kendall LIFETRACE Umbilical Blood Collection Kit
Cleared Date: 03-NOV-2003

BK070037-0 Typenex Medical LLC
303 East Wacker Drive
Suite 311
Chicago, IL 60601
Trade Name: TypeSafe Segment Dispenser
Cleared Date: 05-OCT-2007

BK150351-0 Typenex Medical LLC
303 East Wacker Drive

Suite 311
Chicago, IL 60601
Trade Name: Typesafe 2.0 Segment Piercing Device (Model Number SP0201QD & SP0201QM)
Cleared Date: 28-DEC-2015

BK820012-0 UCLA Tissue Typing Laboratory
1000 Veteran Avenue
Los Angeles, CA 90024
Trade Name: HLA Typing Tray
Cleared Date: 04-MAR-1983

BK970026-0 Utah Medical Products, Inc.
7043 South 300 West
Midvale, UT 84047
Trade Name: Umbilicup
Cleared Date: 28-JAN-1998

BK970027-0 Utah Medical Products, Inc.
7043 South 300 West
Midvale, UT 84047
Trade Name: Umbilicup II Cord Blood System
Cleared Date: 06-JAN-1998

BK010043-0 VEEGEE Scientific
13600 NE 126th Place
Suite A
Kirkland, WA 98034
Trade Name: Atago SP-D2 Refractometer
Cleared Date: 02-JAN-2002

BK870008-0 Val Tech Diagnostics
14 Werner Camp Road
Pittsburgh, PA 15238
Trade Name: Normal Saline-Buffered
Cleared Date: 31-JUL-1987

BK880004-0 Val Tech Diagnostics
14 Werner Camp Road
Pittsburgh, PA 15238
Trade Name: Buffered Normal Saline Concentrate
Cleared Date: 11-APR-1988

BK070044-0 Verax Biomedical Incorporated
148 Bartlett Street
Marlborough, MA 01752
Trade Name: Platelet PGD Controls
Platelet PGD Test
Cleared Date: 17-SEP-2007

BK090028-0 Verax Biomedical Incorporated
148 Bartlett Street
Marlborough, MA 01752
Trade Name: Platelet PGD Test System
Cleared Date: 10-NOV-2009

BK110014-0 Verax Biomedical Incorporated
148 Bartlett Street
Marlborough, MA 01752
Trade Name: Platelet PGD Test System
Cleared Date: 08-SEP-2011

BK140201-0 Verax Biomedical Incorporated
148 Bartlett Street
Marlborough, MA 01752
Trade Name: Platelet PGD(R) Test System
Cleared Date: 13-MAY-2015

BK160087-0 Verax Biomedical Incorporated
148 Bartlett Street
Marlborough, MA 01752
Trade Name: Platelet PGD Test System
Cleared Date: 06-APR-2017

BK120008-0 Vertical Spine, LLC
2201 Marconi Road
Wall, NJ 07719
Trade Name: FIBRINET (R) Autologous PRP System
Cleared Date: 01-AUG-2012
Cleared Under Cascade Medical Enterprises, LLC

BK020005-0 Visible Genetics, Inc.
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 CANADA
Trade Name: Trugene HIV-1 Genotyping Kit and
Open Gene DNA Sequencing System
Cleared Date: 24-APR-2002

BK020042-0 Visible Genetics, Inc.
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 CANADA
Trade Name: TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 07-NOV-2002

BK030015-0 Visible Genetics, Inc.
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 CANADA
Trade Name: TRUGENE HIV-1 Genotyping Kit and

OpenGene DNA Sequencing System
Cleared Date: 14-MAR-2003

BK910010-0 WHITTAKER BIOPRODUCTS, INC.
8830 Biggs Ford Road
Walkersville, MO 21793
Trade Name: ENDOTOXIN CHALLENGE VIALS
Cleared Date: 09-AUG-1991

BK860039-0 Wako Chemicals, USA, Inc.
12300 Ford Road, Suite 130
Dallas, TX 75234
Trade Name: Toxinometer ET-201
Cleared Date: 10-FEB-1987

BK230826-0 WellSky Corporation
11300 Switzer Rd
Overland Park, KS 66210
Trade Name: WellSky Transfusion 2022 R3
Cleared Date: 19-JUL-2023

BK910005-0 Whitman Medical Corporation
990 Raritan Road
Clark, NJ 07066
Trade Name: Safe-T-Vue Irreversible
Temperature Indicator
Cleared Date: 12-MAY-1992

BK220673-0 Wuhan BMS Medicaltech Co., Ltd
5th Floor,Units C/D,Building 9,Area B,Me
, Wuhan CHINA 430206
Trade Name: Sterile Tube Welder (Model:
STW6810-RFID)
Cleared Date: 24-OCT-2022

BK950059-0 Wyndgate Technologies
11121 Sun Center Drive
Suite C
Rancho Cordova, CA 95670
Trade Name: Safe Trace
Cleared Date: 14-APR-1997

BK980023-0 Wyndgate Technologies
11060 White Rock Road
Suite 200
Rancho Cordova, CA 95670
Trade Name: SafeTrace TX, version 1.0
Cleared Date: 29-JAN-1999

BK070010-0 Wyndgate Technologies

4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: ElDorado Donor Doc - 1.0.0
Cleared Date: 23-MAY-2007

BK070064-0 Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: ElDorado Donor - 1.0.0
Cleared Date: 13-FEB-2008

BK090026-0 Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: Safe Trace Tx
Cleared Date: 03-SEP-2009

BK090033-0 Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: ElDorodo Donor Doc
Cleared Date: 28-OCT-2009

BK090063-0 Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: Test Result Interface for ElDorado
Donor
Cleared Date: 20-NOV-2009

BK100002-0 Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: Component Manufacturing Interface
for ElDorado Donor
Cleared Date: 24-FEB-2010

BK230818-0 YTS Global Inc
7406 Alban Station Ct
Springfield, VA 22150-2310
Trade Name: Dr. PRP
Cleared Date: 31-MAY-2023

BK860005-0 bioMerieux, Inc.

5300 S. Portland Avenue
Oklahoma City, OK 73119
Trade Name: Plasma Collection Bag
Cleared Date: 19-DEC-1986
Cleared Under BioMerieux, Inc.

BK870019-0 bioMerieux, Inc.
5300 S. Portland Avenue
Oklahoma City, OK 73119
Trade Name: Quik-Chek
Cleared Date: 19-MAY-1988
Cleared Under BioMerieux, Inc.

BK880003-0 bioMerieux, Inc.
5300 S. Portland Avenue
Oklahoma City, OK 73119
Trade Name: Therapeutic Plasmapheresis
Collection Bag
Cleared Date: 11-MAR-1988
Cleared Under BioMerieux, Inc.

BK920037-0 bioMerieux, Inc.
5300 S. Portland Avenue
Oklahoma City, OK 73119
Trade Name: PEG+
Cleared Date: 21-OCT-1993
Cleared Under BioMerieux, Inc.

BK960026-0 bioMerieux, Inc.
100 Akzo Avenue
Durham, NC 27712
Trade Name: Status Symbol TM II System
Software
Cleared Date: 16-MAR-1999
Cleared Under Organon Teknika Corporation

BK000042-0 bioMerieux, Inc.
100 Akzo Avenue
Durham, NC 27712
Trade Name: BacT/ALERT Culture Bottles
Cleared Date: 15-FEB-2002
Cleared Under BioMerieux, Inc.

BK020022-0 bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT SN Culture Bottle
Cleared Date: 10-OCT-2002
Cleared Under BioMerieux, Inc.

BK020023-0 bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT SA Culture Bottle
Cleared Date: 10-OCT-2002
Cleared Under BioMerieux, Inc.

BK020060-0 bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: NuclieSens HIV-1 QT RNA External Controls
Cleared Date: 18-DEC-2002
Cleared Under BioMerieux, Inc.

BK030034-0 bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPN Culture Bottle
Cleared Date: 18-JUL-2003
Cleared Under BioMerieux, Inc.

BK030035-0 bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPA Culture Bottle
Cleared Date: 06-AUG-2003
Cleared Under BioMerieux, Inc.

BK030075-0 bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPN Culture Bottles
Cleared Date: 08-MAR-2004
Cleared Under BioMerieux, Inc.

BK030076-0 bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPA Culture Bottles
Cleared Date: 08-MAR-2004
Cleared Under BioMerieux, Inc.

BK050037-0 bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPA Culture Bottle
Cleared Date: 27-DEC-2005
Cleared Under BioMerieux, Inc.

BK050043-0 bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPN Culture Bottle
Cleared Date: 27-DEC-2005
Cleared Under BioMerieux, Inc.

BK170142-0 bioMerieux, Inc.
595 Anglum Road
Hazelwood, MO 63042
Trade Name: BacT/ALERT BPA Culture Bottle
BacT/ALERT BPN Culture Bottle
Cleared Date: 01-FEB-2018

BK180266-0 bioMerieux, Inc.
595 Anglum Road
Hazelwood, MO 63042
Trade Name: BACT/ALERT BPA Culture Bottle
BACT/ALERT BPN Culture Bottle
Cleared Date: 29-NOV-2018

BK200472-0 bioMerieux, Inc.
595 Anglum Road
Hazelwood, MO 63042
Trade Name: BACT/ALERT BPA Culture Bottle
BACT/ALERT BPN Culture Bottle
Cleared Date: 20-MAY-2020

BK040018-0 sienna partners
P.O. Box 103
Baldwin, MD 21013
Trade Name: Vacuette EDTA K2 tube; Vacuette
EDTA K3 tube
Cleared Date: 28-JUL-2004