Currently Cleared CBER 510(k)s by Applicant As of 30-JUN-2019

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

BK050005-0 ALBA Bioscience Limited (doing business as Quotient)
21 Ellen's Glen Road  
Liberton, Edinburgh  
EH17 7QT  
Scotland, UNITED KINGDOM, United Kingdom EH17 7QT  

Trade Name: Quant-Rho FITC Anti-D for Fetal Cell Assay  
Cleared Date: 27-SEP-2005  
Cleared Under ALBA Bioscience

BK070033-0  ALBA Bioscience Limited (doing business as Quotient)  
21 Ellen's Glen Road  
Liberton, Edinburgh  
EH17 7QT  
Scotland, UNITED KINGDOM, United Kingdom EH17 7QT  
Trade Name: AlbaQ-Chek Simulated Whole Blood Controls  
Cleared Date: 27-JUL-2007  
Cleared Under ALBA Bioscience

BK080027-0  ALBA Bioscience Limited (doing business as Quotient)  
21 Ellen's Glen Road  
Liberton, Edinburgh  
EH17 7QT  
Scotland, UNITED KINGDOM, United Kingdom EH17 7QT  
Trade Name: ALBAcheck - BGS Reagent Control for Anti-D  
Cleared Date: 29-JUL-2008  
Cleared Under ALBA Bioscience

BK080051-0  ALBA Bioscience Limited (doing business as Quotient)  
21 Ellen's Glen Road  
Liberton, Edinburgh  
EH17 7QT  
Scotland, UNITED KINGDOM, United Kingdom EH17 7QT  
Trade Name: FETALSCREEN  
Cleared Date: 08-APR-2009  
Cleared Under ALBA Bioscience

BK090030-0  ALBA Bioscience Limited (doing business as Quotient)  
21 Ellen's Glen Road  
Liberton, Edinburgh  
EH17 7QT  
Scotland, UNITED KINGDOM, United Kingdom EH17 7QT  
Trade Name: ALBAcheck - BGS Whole Blood Controls-SP  
Cleared Date: 14-JUN-2010  
Cleared Under ALBA Bioscience

BK10005-0  ALBA Bioscience Limited (doing business as Quotient)  
21 Ellen's Glen Road  
Liberton, Edinburgh  
EH17 7QT  
Scotland, UNITED KINGDOM, United Kingdom EH17 7QT  
Trade Name: ALBAcyte IgG Sensitized Red Blood Cells  
Cleared Date: 26-AUG-2010  
Cleared Under ALBA Bioscience

BK140144-0  ALBA Bioscience Limited (doing business as Quotient)  
21 Ellen's Glen Road  
Liberton, Edinburgh  
EH17 7QT  
Scotland, UNITED KINGDOM, United Kingdom EH17 7QT  
Trade Name: ALBAzyme(TM) Papain Solution Kit  
Cleared Date: 17-SEP-2014
ALBA Bioscience Limited (doing business as Quotient)

21 Ellen’s Glen Road
Liberton, Edinburgh
EH17 7QT
Scotland, UNITED KINGDOM, United Kingdom EH17 7QT

Trade Name: ALBAcyte® C3 Coated Red Blood Cells
Cleared Date: 04-MAR-2015

ALBA Bioscience Limited (doing business as Quotient)

21 Ellen’s Glen Road
Liberton, Edinburgh
EH17 7QT
Scotland, UNITED KINGDOM, United Kingdom EH17 7QT

Trade Name: ALBAsure® QC Kit
Cleared Date: 01-APR-2015

ALBA Bioscience Limited (doing business as Quotient)

21 Ellen’s Glen Road
Liberton, Edinburgh
EH17 7QT
Scotland, UNITED KINGDOM, United Kingdom EH17 7QT

Trade Name: ORTHO(TM) Sera Papain
Cleared Date: 20-OCT-2015

APEX Biologix

5650 South Green St
Murray, UT 84123

Trade Name: XCELL PRP™ Platelet Concentrating System 60ml
Cleared Date: 05-APR-2019

ARK-Bio-Medical Canada Corp.

#671 Rustico Road
Winsloe, Canada C1E 1Z2

Trade Name: WesLabs Model 601
Cleared Date: 15-NOV-1989
Cleared Under Rush Enterprises, Inc.

Abbott Laboratories

100 Abbott Park Road
Abbott Park, IL 60064-3500

Trade Name: Abbott Anti-HBs Panel
Cleared Date: 11-OCT-1990

Abbott Laboratories

100 Abbott Park Road
Abbott Park, IL 60064-3500

Trade Name: Abbott CMV Total AB EIA
Cleared Date: 22-DEC-1995

Abbott Laboratories

100 Abbott Park Road
Abbott Park, IL 60064-3500

Trade Name: Abbott Apheresis Results Tracking System/AARTS
Cleared Date: 24-JUN-1998

Abbott Laboratories

100 Abbott Park Road
Abbott Park, IL 60064-3500

Trade Name: Abbott DMS II Data Management System
Cleared Date: 12-AUG-1998
Trade Name: ABBOTT PRISM System
Cleared Date: 14-JUN-1999

Trade Name: ABBOTT PRISM Retest Server - 1.0
Cleared Date: 17-JUL-2002

Trade Name: Abbott PRISM Retest Server
Cleared Date: 07-JUN-2006

Trade Name: ABBOTT PRISM Director V2.0
Cleared Date: 24-APR-2008

Trade Name: ABBOTT PRISM Director
Cleared Date: 14-MAY-2013

Trade Name: Dade Rh Control Reagent
Cleared Date: 31-MAR-1981

Trade Name: Trans-Type Reagents
Cleared Date: 29-OCT-1982

Trade Name: Polycation Potentiator System
Cleared Date: 06-MAY-1983

Trade Name: Data-Fi Thrombin Reagent
Cleared Date: 16-JAN-1987

Trade Name: Ackrad Blood Warming Assembly
Cleared Date: 21-SEP-1990

Trade Name: 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

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

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

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

BK9500014-0 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 Bromelain
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
Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name: Amtec Anti-N Lectin
Cleared Date: 18-SEP-1987

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

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

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

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

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

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

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

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

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

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: ASI Manager-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

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

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

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

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
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<th>BK050062-0</th>
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<td>Trade Name:</td>
<td>BD HLA-B27 kit</td>
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<td>Trade Name:</td>
<td>BD Stem Cell Enumeration Kit</td>
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<td>BD FACSVia System with the BD Leucocount reagent Assay</td>
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<td>Trade Name:</td>
<td>Plasma Preparation Tube - PPT</td>
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<td>VACUTAINER Brand PLUS (Plastic) Blood Collection Tube with EDTA Anticoagulant</td>
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<td>07-JUN-1999</td>
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<td>BMT Model 24 Bloodmixer</td>
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<td>True-Pulse Infusion Catheter</td>
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<td>Cleared Date:</td>
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| 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
Round Lake, 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
San Jose, CA 95131
Trade Name: ProCount Progenitor Cell Enumeration Kit
Cleared Date: 04-JUN-1998
BK970038-0 Becton Dickinson Immunocytometry Systems
2350 Quine Drive
San Jose, CA 95131
Trade Name: Procount Software
Cleared Date: 04-FEB-1999
BK970046-0 Becton Dickinson Immunocytometry Systems
2350 Quine Drive
San Jose, CA 95131
Trade Name: LeucoCOUNT Reagent
Cleared Date: 14-AUG-1998
BK950068-0 Becton, Dickinson & Company
1 Becton Drive, MC 300
Franklin Lakes, NJ 07417-1885
Trade Name: CMV Scan Card Test
Cleared Date: 22-DEC-1995
BK040030-0 Becton, Dickinson & Company
1 Becton Drive, MC 300
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, MC 300
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, MC 300
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 Lovetown Circle, MC 694
Sparks, MD 21152-0999
Trade Name: BD BACTEC™ Platelet Aerobic/F Culture tubes
BD BACTEC™ Platelet Anaerobic/F Culture Vials
Cleared Date: 08-AUG-2018
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

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

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
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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

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

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

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

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

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 III Platelet Concentration Separation Kit with ACD-A
Plasmapher 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
Trade Name: STELLer CD34 Assay  
Cleared Date: 18-AUG-1998  
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 Separation 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 Dreieich, 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
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

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.
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

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

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

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

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

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 Platelet Filtration and Storage Set (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

BK090054-0  Calimex USA Corporation
258 Hollister Avenue
Alameda, CA 94501
Trade Name: Picture-ID
BK110070-0  Calimex USA Corporation  
258 Hollister Avenue  
Alameda, CA 94501  
Trade Name: eOrders, Version 1 - 1  
Cleared Date: 17-FEB-2012

BK120035-0  Calimex USA Corporation  
258 Hollister Avenue  
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 Bullet Infusion Cathether  
Cleared Date: 27-FEB-1995

BK940028-0  Cardiovascular Dynamics, Inc.  
15 Hammond Suite 307  
Irvine, CA 92718  
Trade Name: CVD Bullet 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

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 FiBRI NET System
Cleared Date: 16-FEB-2006

BK120009-0  Cascade Medical Enterprises, LLC
20 Greenup Court
Wayne, NJ 07470
Trade Name: FiBRI NET (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
Centocor, Inc.
200 Great Valley Parkway
Malvern, PA 19355
Trade Name: CAPTIA CMV-TA EIA
Cleared Date: 22-MAR-1995

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

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

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

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

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

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

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

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

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 Platelets and Plasma
Cleared Date: 21-JUN-1990
<table>
<thead>
<tr>
<th>Document ID</th>
<th>Company Name</th>
<th>Address</th>
<th>Trade Name</th>
<th>Cleared Date</th>
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<tr>
<td>BK90003-0</td>
<td>Cobe Laboratories, Inc.</td>
<td>1185 Oak Street Lakewood, CO 80215</td>
<td>Trade Name: COBE Spectra: Change in Anticoagulant Ratio</td>
<td>14-NOV-1990</td>
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<td>BK90004-0</td>
<td>Cobe Laboratories, Inc.</td>
<td>1185 Oak Street Lakewood, CO 80215</td>
<td>Trade Name: COBE Spectra: Single Needle System</td>
<td>21-JUN-1990</td>
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<tr>
<td>BK910020-0</td>
<td>Cobe Laboratories, Inc.</td>
<td>1185 Oak Street Lakewood, CO 80215</td>
<td>Trade Name: COBE SPECTRATHERM</td>
<td>02-NOV-1992</td>
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<tr>
<td>BK920011-0</td>
<td>Cobe Laboratories, Inc.</td>
<td>1185 Oak Street Lakewood, CO 80215</td>
<td>Trade Name: Cobe Spectra with PCM</td>
<td>15-MAY-1995</td>
</tr>
<tr>
<td>BK920036-0</td>
<td>Cobe Laboratories, Inc.</td>
<td>1185 Oak Street Lakewood, CO 80215</td>
<td>Trade Name: COBE Spectra Single-Needle Extended Life Platelet (ELP) Set</td>
<td>06-APR-1993</td>
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<tr>
<td>BK930017-0</td>
<td>Cobe Laboratories, Inc.</td>
<td>1185 Oak Street Lakewood, CO 80215</td>
<td>Trade Name: COBE Spectra Apheresis System (Triple Platelet)</td>
<td>27-JUL-1994</td>
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<tr>
<td>BK940016-0</td>
<td>Cobe Laboratories, Inc.</td>
<td>1185 Oak Street Lakewood, CO 80215</td>
<td>Trade Name: COBE Spectra Version 4</td>
<td>20-SEP-1994</td>
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<td>BK950030-0</td>
<td>Cobe Laboratories, Inc.</td>
<td>1185 Oak Street Lakewood, CO 80215</td>
<td>Trade Name: COBE Spectra Extended Life Platelet Set</td>
<td>15-FEB-1996</td>
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<td>BK970007-0</td>
<td>Community Bio-Resources, Inc.</td>
<td>2197 Parkway Lake Drive Hoover, AL 35244</td>
<td>Trade Name: Donor Information System - 1.0</td>
<td>09-APR-1997</td>
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<td>BK960060-0</td>
<td>Community Blood Center of Greater Kansas City</td>
<td>4040 Main Street Kansas City, MO 64111</td>
<td>Trade Name: CBC Blood System, Version 1.2</td>
<td>20-NOV-1997</td>
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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-15
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

BK850009-0  Cordis Laboratories, Inc.
              2140 North Miami Avenue
              Miami, FL 33127
Trade Name: CORDIA HTLV-I
Cleared Date: 03-OCT-1985

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

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: CytoTherm (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
55 Heritage Drive, Suite 115
Jupiter, FL 33458
Trade Name: Autologous Platelet Integrated Concentration (“APIC”) System
Cleared Date: 17-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  DENC0, INC.
P.O. BOX 9600
Wilmington, DE 19809
Trade Name: Total Containment Device
Cleared Date: 18-APR-2000

BK990041-0  DENC0, INC.
P.O. BOX 9600
Wilmington, DE 19809
Trade Name: Total Containment Device
Cleared Date: 21-DEC-1999

BK160084-0  DIAGAST
Parc Eurasanté
251, Avenue Eugéne Avinée
BP 9
LOOS Cedex, France 59374
Trade Name: Neg Control
Cleared Date: 02-FEB-2018

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 v8.12
Cleared Date: 17-OCT-2012
Cleared Under Data Innovations Inc.

BK120051-0  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.

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
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 (VB ECS) - 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 (VB ECS) - 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 (VB ECS)  
Cleared Date: 01-OCT-2018

BK830025-0  Dia Tech  
2525 Shader Road  
Orlando, FL 3288  
Trade Name: DiaCent 2 Automated Cell Washer/Centrifuge  
Cleared Date: 10-JAN-1984

BK840001-0  Dia Tech  
2525 Shader Road  
Orlando, FL 3288  
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

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: Grifols Diluent  
Cleared Date: 19-JUL-2013
BK120046-0 Diagnostic Grifols, S.A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, Spain 08150
Trade Name: DG Spin
Cleared Date: 19-JUL-2013

BK130025-0 Diagnostic Grifols, S.A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, Spain 08150
Trade Name: DG THERM
Cleared Date: 19-JUL-2013

BK130067-0 Diagnostic Grifols, S.A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, Spain 08150
Trade Name: WADiana(R) Compact
Cleared Date: 30-AUG-2013

BK140101-0 Diagnostic Grifols, S.A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, Spain 08150
Trade Name: Erytra(R)
Cleared Date: 17-JAN-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
Cleared Date: 01-NOV-2017

BK180260-0 Diagnostic Grifols, S.A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, Spain 08150
Trade Name: Erytra Efleixis
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

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
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

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

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 cm Flexible)  
Cleared Date: 05-JUN-2019

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

BK860018-0 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA Plaza)
Tucson, AZ 85716
Trade Name: SEBRA Model 1150 (Blood Weight 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

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 (mononuclear 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: 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  
AMI CUS 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

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

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 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

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

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

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

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

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

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

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

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

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

Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma EGA Kit
Cleared Date: 21-JUL-1997

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

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

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

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

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

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

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

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

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

BK140187-0  Genesis BPS, 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

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
Suite 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
Suite 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
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<thead>
<tr>
<th>Set (Blow Molded Bowl)</th>
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<tbody>
<tr>
<td>BK930013-0 Haemonetics Corporation</td>
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<td>Trade Name: MCS Plus &amp; Disp. Sets,</td>
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<td>Trade Name: Red Cell and Plasma</td>
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<td>Apheresis Set/ FOR USE WITH MCP</td>
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<td>PLUS</td>
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<td>Storage Plt Collection Set</td>
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<td>Trade Name: ESP White Cell Filter</td>
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<td>(No. 790F)</td>
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<td>Trade Name: Double Product</td>
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<td>Collection (SDP-3)</td>
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<td>Trade Name: Red Blood Cell and</td>
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<td>Plasma Collection Set for the MCS</td>
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<td>Plus #823</td>
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<td>Trade Name: Double Unit Red Blood</td>
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<td>Cell Apheresis Set MCS #833</td>
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<td>BK960022-0 Haemonetics Corporation</td>
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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 Plasticized PVC
Extended Storage Platelet Bag
Cleared Date: 07-JAN-1999

BK900002-0 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
Trade Name: Haemonetics LN832F
Two Unit Red Cells Disposable Set with Leukocyte reduction Filter
Cleared Date: 27-OCT-2000

Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Cleared Date: 09-APR-2001

Trade Name: Haemonetics LN832F
Cleared Date: 09-APR-2001

Trade Name: MCS+ Mobile Collection System
Cleared Date: 20-DEC-2002

Trade Name: Plasma Pooling Bottle II
Cleared Date: 29-MAR-2002

Trade Name: Haemonetics Model 215 Automated Glycerolization / Deglycerolization and Cell Washing System
Cleared Date: 10-SEP-2003

Trade Name: Haemonetics Model 215 Automated Glycerolization/deglycerolization System
Cleared Date: 10-DEC-2003

Trade Name: Haemonetics LN994CF-CPP-BA Extended Storage Platelet and Plasma Apheresis Set
Cleared Date: 09-JAN-2004

Trade Name: Haemonetics 4mL Sampling System
Cleared Date: 27-FEB-2004

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
<table>
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<th>ID</th>
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<th>Cleared Date</th>
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<td>Haemonetics Corporation</td>
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<td>PCS2 Plasma Collection System</td>
<td>02-JUN-2004</td>
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<td>Haemonetics Corporation</td>
<td>400 Wood Road, Braintree, MA</td>
<td>Haemonetics MCS+8150 Apheresis System</td>
<td>12-JUL-2004</td>
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<td>BK040077-0</td>
<td>Haemonetics Corporation</td>
<td>400 Wood Road, Braintree, MA</td>
<td>Haemonetics Model 215 Automated Glycerolization/Deglycerolization System</td>
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<td>BK050006-0</td>
<td>Haemonetics Corporation</td>
<td>400 Wood Road, Braintree, MA</td>
<td>ACP 215 Glycerolization/Deglycerolization System</td>
<td>14-APR-2005</td>
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<td>400 Wood Road, Braintree, MA</td>
<td>MCS+9000, SDP revision E software, 994CF-CPP series disposable sets</td>
<td>21-NOV-2005</td>
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<td>Haemonetics Corporation</td>
<td>400 Wood Road, Braintree, MA</td>
<td>Haemonetics MCS+ 8150 Apheresis System</td>
<td>27-SEP-2005</td>
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<td>BK060008-0</td>
<td>Haemonetics Corporation</td>
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<td>Haemonetics ACP 215 Glycerolization/Deglycerolization System</td>
<td>23-MAY-2006</td>
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<td>400 Wood Road, Braintree, MA</td>
<td>Haemonetics MCS+ 8150 Apheresis System</td>
<td>23-MAY-2006</td>
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<td>BK060033-0</td>
<td>Haemonetics Corporation</td>
<td>400 Wood Road, Braintree, MA</td>
<td>Haemonetics PCS 2 Plasma Collection System, Wireless (W) Capable Modification</td>
<td>27-MAR-2008</td>
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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: El Dorado 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
Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: PCS 300 Plasma Collection System
Cleared Date: 25-JUL-2017

Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: PCS 300 Plasma Collection System
Cleared Date: 27-MAR-2018

Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Safe Trace Tx - 4.0.0
SafeTrace Tx
Cleared Date: 07-AUG-2018

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

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

Haemonetics Corporation Software Solutions
1630 Industrial Park Street
Covina, CA 91722-9144
Trade Name: MCS+B150 System - Wireless
Cleared Date: 20-FEB-2009
Cleared Under Haemonetics Corporation

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

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

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

Haemonetics Corporation Software Solutions
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: El Dorado 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: 08-FEB-1983
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
Cleared Date: 28-SEP-2005
Cleared Under Medsep Corporation

BK050074-0 Haemonetics Manufacturing Inc.
<table>
<thead>
<tr>
<th>File Number</th>
<th>Company Name</th>
<th>Address</th>
<th>Trade Name</th>
<th>Cleared Date</th>
<th>Cleared Under</th>
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<tbody>
<tr>
<td>BK050075-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road</td>
<td>Pall Acrodose PL System</td>
<td>26-JAN-2006</td>
<td>Medsep Corporation</td>
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<tr>
<td>BK060040-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road</td>
<td>Pall eBDS</td>
<td>20-DEC-2005</td>
<td>Medsep Corporation</td>
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<td>BK060044-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road</td>
<td>Pall Acrodose PL System, Platelet Pool and Store Set with in-line Leukocyte Reduction Filter</td>
<td>12-APR-2007</td>
<td>Medsep Corporation</td>
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<tr>
<td>BK060045-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road</td>
<td>Pall Acrodose PL System, Platelet Pool and Store Set</td>
<td>01-SEP-2006</td>
<td>Medsep Corporation</td>
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<tr>
<td>BK060047-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road</td>
<td>Pall eBDS</td>
<td>04-APR-2007</td>
<td>Medsep Corporation</td>
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<td>BK070004-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road</td>
<td>Pall eBDS</td>
<td>26-JUN-2007</td>
<td>Medsep Corporation</td>
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<tr>
<td>BK070056-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road</td>
<td>Pall Acrodose PLus System Platelet Pool and Store Set with in-line Leukocyte Reduction Filter and eBDS</td>
<td>27-SEP-2007</td>
<td>Medsep Corporation</td>
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<tr>
<td>BK070057-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road</td>
<td>Pall eBDS</td>
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<td>Medsep Corporation</td>
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</table>
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
40 Grissom Road
Plymouth, MA 02360
Trade Name: Harvest PRP Separation System
Cleared Date: 05-FEB-2001

BK100059-0 Harvest Technologies
40 Grissom Road
Plymouth, MA 02360
Trade Name: Harvest PRP Separation System
Cleared Date: 18-NOV-2010

BK120038-0 Harvest Technologies
40 Grissom Road
Plymouth, MA 02360
Trade Name: Harvest PRP Separation System with ACDA(30ml)
Cleared Date: 28-SEP-2012

BK130068-0 Harvest Technologies
40 Grissom Road
Plymouth, MA 02360
Trade Name: SmartPrep2 System
Cleared Date: 24-MAR-2014

BK170136-0 Healeon Medical, Inc.
1111 Rancho Conejo Blvd #204
Newbury Park, CA 91320
Trade Name: Healeon PRP Platelet Preparation
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 iCAS!
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 iCAS!
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: Olympus 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

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

BK950008-0 Hemasure, Inc.
140 Locke Drive
Marlborough, MA 01752
Trade Name: LeukoNet Pre Storage Leukodepletion Filtration 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

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

633 Davis Drive
Suite 100
Morrisville, NC 27560
Trade Name: MQC-CAT
Cleared Date: 30-MAR-2017

Hemo bioscience
633 Davis Drive
Suite 100
Morrisville, NC 27560
Trade Name: HemoCue Hb 301 System
Cleared Date: 14-APR-2006

HemoCue AB
40 Empire Drive
Lake Forest, CA 92630
Trade Name: HemoCue Hb 301 System
Cleared Date: 05-OCT-2006

HemoCue AB
Kuvettgatan 1
Angelholm, Sweden SE-262 71
Trade Name: HemoCue Hb 301 System
Cleared Date: 09-APR-2001

HemoCue, Incorporated
9229 Cranford Drive
Potomac, MD 20854
Trade Name: HemoCue Low Hemoglobin Analyzing System
Cleared Date: 17-APR-2003

HemoCue, Incorporated
9229 Cranford Drive
Potomac, MD 20854
Trade Name: Donor Hemoglobin Checker System
Cleared Date: 19-DEC-2003

Hemosystem, S.A.
45, Cours Gouffe
13006 Marseille, France
Trade Name: Scansystem bacterial detection device
Cleared Date: 23-SEP-2004

Heraeus Inc.
111A Corporate Blvd, S.
Plainfield, NJ 07080
Trade Name: Cryofuge 6000
Cleared Date: 05-NOV-1992

I. B. G. Systems Inc.
P.O. Box 5306
Laytonsville, MD 20882
Trade Name: Inverness Blood Grouping System
Cleared Date: 20-SEP-1990

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

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

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-DQA1/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
  Norcross, GA 30091-5625
Trade Name: Checkcell
Cleared Date: 15-DEC-1982

BK830004-0 Immucor, Inc.
  3130 Gateway Drive
  Norcross, GA 30091-5625
Trade Name: 22% Bovine Albumin
Cleared Date: 17-MAR-1983

BK830005-0 Immucor, Inc.
  3130 Gateway Drive
  Norcross, GA 30091-5625
Trade Name: 30% Bovine Albumin
Cleared Date: 17-MAR-1983
Trade Name: Low Ionic Strength Solution (LISS)
Cleared Date: 11-MAY-1983

Trade Name: Rh-Hr Control
Cleared Date: 19-JUL-1983

Trade Name: Anti-N Lectin
Cleared Date: 07-NOV-1983

Trade Name: ImmuAdd
Cleared Date: 07-NOV-1983

Trade Name: Anti-A1 Lectin
Cleared Date: 07-NOV-1983

Trade Name: corQc Test System
Cleared Date: 08-NOV-1984

Trade Name: Capture P Solid Phase System
Cleared Date: 06-OCT-1986

Trade Name: Capture-R (I and II)
Cleared Date: 03-JUN-1988

Trade Name: Capture-R (Pooled)
Cleared Date: 03-JUN-1988
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

BK900014-0 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 R  
Cleared Date: 24-OCT-1997
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: Hemagglutination/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
ABS2000 with Version1.00.30A SR-2
**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
Trade Name: Galileo Automated Blood Bank System with assays to perform red blood cell phenotyping
Cleared Date: 28-SEP-2007

Trade Name: Immucor's WB corQC
Cleared Date: 16-NOV-2007

Trade Name: Galileo with Reverse ABO Group Assay
Cleared Date: 30-NOV-2007

Trade Name: Automated Blood Bank Analyzer
Cleared Date: 05-FEB-2009

Trade Name: Galileo
Cleared Date: 09-JUL-2010

Trade Name: Galileo Neo
Cleared Date: 29-APR-2010

Trade Name: Galileo Neo
Cleared Date: 23-AUG-2010

Trade Name: Checkcell
Cleared Date: 03-OCT-2011

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
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

BK840004-0 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

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

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

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 1 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

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

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
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

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

BK030008-0 MacoProductions S.A.S.
c/o Hoppe Regulatory Consultants
2335 massey Lane
Decatur, GA 30033
Trade Name: Leucolab LCG2 Leukoreduction System for Red Blood Cells
Cleared Date: 02-MAY-2003

BK050041-0 MacoProductions S.A.S.
c/o Hoppe Regulatory Consultants
2335 massey Lane
Decatur, GA 30033
Trade Name: Leucolab LCG2 Leukoreduction System for AS-1, AS-3, and AS-5 Red Blood Cells
Cleared Date: 12-OCT-2005

BK080060-0 MacoProductions S.A.S.
1733 Canton Lane
Suite 103
Marietta, GA 30062-2679
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.
3675 Crestwood Parkway
Suite 260
Duluth, GA 30096
Trade Name: Leucolab LCG2 Leukoreduction Systems for AS-1 Red Blood Cells
Trade Name: Leucolab LCG2 Leukoreduction Systems for AS-1 and AS-3 Red Blood Cells
Trade Name: 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

BK900051-0 McKesson Provider Technologies
5995 Windward Parkway
Alpharetta, GA 30005
Trade Name: Horizon MobileCare Transfusion
Cleared Date: 28-MAY-2010

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 60559
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: LifeTrak / 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(TM) 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 with 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

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

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
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<tr>
<th>Document ID</th>
<th>Company Name</th>
<th>Address</th>
<th>Trade Name</th>
<th>Clear Date</th>
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<tr>
<td>BK950028-0</td>
<td>Micro Typing Systems Inc.</td>
<td>1295 S.W. 29th Ave., Pompano Beach, FL 33069</td>
<td>MTS Dispenser (0.5ml and 1.0ml)</td>
<td>27-JUN-1995</td>
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<td>BK960013-0</td>
<td>Micro Typing Systems Inc.</td>
<td>1295 S.W. 29th Ave., Pompano Beach, FL 33069</td>
<td>MTS-Centrifuge Model NU 9310</td>
<td>15-APR-1996</td>
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<td>BK980016-0</td>
<td>Micro Typing Systems Inc.</td>
<td>1295 S.W. 29th Ave., Pompano Beach, FL 33069</td>
<td>ID-Tipmaster</td>
<td>29-OCT-1998</td>
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<td>BK990012-0</td>
<td>Micro Typing Systems Inc.</td>
<td>1295 S.W. 29th Ave., Pompano Beach, FL 33069</td>
<td>MTS Reader M</td>
<td>19-NOV-1999</td>
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<td>BK000018-0</td>
<td>Micro Typing Systems Inc.</td>
<td>1295 S.W. 29th Ave., Pompano Beach, FL 33069</td>
<td>MTS Reader SA</td>
<td>21-NOV-2000</td>
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<td>BK010021-0</td>
<td>Micro Typing Systems Inc.</td>
<td>1295 S.W. 29th Ave., Pompano Beach, FL 33069</td>
<td>MTS Incubator II</td>
<td>01-OCT-2001</td>
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<td>BK030023-0</td>
<td>Micro Typing Systems Inc.</td>
<td>1295 S.W. 29th Ave., Pompano Beach, FL 33069</td>
<td>Ortho ProVue, Software Version: 2.10</td>
<td>14-MAY-2003</td>
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<tr>
<td>BK090013-0</td>
<td>Micro Typing Systems Inc.</td>
<td>1295 S.W. 29th Ave., Pompano Beach, FL 33069</td>
<td>ORTHO ProVue, version 3.1</td>
<td>04-JUN-2009</td>
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<td>BK110029-0</td>
<td>Micro Typing Systems Inc.</td>
<td>1295 S.W. 29th Ave., Pompano Beach, FL 33069</td>
<td>Ortho ProVue Analyzer Version 3.1 Patch 1 (V3.1.1)</td>
<td>14-JUL-2011</td>
</tr>
<tr>
<td>BK150280-0</td>
<td>Micro Typing Systems Inc.</td>
<td>1295 S.W. 29th Ave., Pompano Beach, FL 33069</td>
<td>MTS Buffered Gel Card MTS Monoclonal Control Card</td>
<td>14-AUG-2015</td>
</tr>
<tr>
<td>BK160061-0</td>
<td>Micro Typing Systems Inc.</td>
<td>1295 S.W. 29th Ave.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Pompano Beach, FL 33069
Trade Name: MTS TM Buffered Gel Card
MTS TM Monoclonal Control Card
Cleared Date: 21-OCT-2016

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

BK090020-0 Miltenyi Biotec, Inc.
120 Presidential Way
Suite 305
Woburn, MA 01801
Trade Name: CryoMACS Freezing Bag
Cleared Date: 13-JAN-2010

BK030065-0 Mississippi Blood Services, Inc.
1995 Lakeland Drive
Jackson, MS 39216
Trade Name: WebLab Online Laboratory System -
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 - Compascuum, Netherlands  
Trade Name: Compomat  
Cleared Date: 30-MAR-1992

BK930018-0  NPBI  
Runde ZZ 41, 7881 HM Emmer Compascuum  
Emmer - Compascuum, Netherlands  
Trade Name: Blood Collection Mixer MW 5001  
Cleared Date: 24-JUL-1994

BK930020-0  NPBI  
Runde ZZ 41, 7881 HM Emmer Compascuum  
Emmer - Compascuum, Netherlands  
Trade Name: Biotrans Separator  
Cleared Date: 27-JUL-1994

BK940061-0  NPBI  
Runde ZZ 41, 7881 HM Emmer Compascuum  
Emmer - Compascuum, Netherlands  
Trade Name: Composeal Mobile and Composeal Universal  
Cleared Date: 26-JAN-1995

BK950035-0  NPBI  
Runde ZZ 41, 7881 HM Emmer Compascuum  
Emmer - Compascuum, Netherlands  
Trade Name: Compostool  
Cleared Date: 27-SEP-1995

BK960084-0  NPBI  
Runde ZZ 41, 7881 HM Emmer Compascuum  
Emmer - Compascuum, 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

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

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
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, Route 22 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(TM) 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
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

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
P.O. Box 350
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
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name: Simwash
Cleared Date: 13-APR-1983

BK830023-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
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
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name: ORTHO Cell Suspension Tube
Cleared Date: 16-NOV-1984
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 Biostor? 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 Trial
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 Trial
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

BK060056-0 Prescott Ideas LLC
8960 E. Anna Place
Tucson, AZ 85710
Trade Name: Antibody Check - 4.1
Cleared Date: 23-APR-2007

BK140119-0 ProFibrix BV
Darwinweg 24
Leiden, Netherlands
Trade Name: RaplixaSpray Device
Cleared Date: 30-APR-2015

BK170092-0 Progenika Biopharma, S.A.
Ibaiabal bidea, Edificio 504
Parque Tecnologico 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

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
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

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

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

ROCHE BIOMEDICAL LABORATORIES, INC.
112 ORANGE DRIVE
ELON COLLEGE, NC 27244
Trade Name: HLA CLASS I PHENOTYPING TRAYS
Cleared Date: 06-JAN-1992

Reagent Laboratory, Inc.
300 East Ottawa Avenue
Louisville, KY 40209
Trade Name: Sodium Chloride 1.3%
Cleared Date: 01-JUN-1987

Reapplix Aps
Blokken 45
Birkerod, Denmark
Trade Name: 3C Patch System
Cleared Date: 24-FEB-2016

Reapplix Aps
Blokken 45
Birkerod, Denmark
Trade Name: 3C Patch System
Cleared Date: 04-APR-2017

RedDress Ltd
Shkedim Street 11
Pardes Hanna, Israel 370110
Trade Name: RD1 System
Cleared Date: 14-JUN-2018

RegenLab SA
3428 Avenue Marcil
Montreal, Quebec Canada H4A 2Z3
Trade Name: RegenKit-THT
Cleared Date: 18-MAY-2010
Cleared Under RegenLab SARL

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

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

BK020018-0  Roche Molecular Systems, Inc.
4300 Hacienda Drive
| BK020025-0 | Roche Molecular Systems, Inc. |
| 4300 Hacienda Drive |
| Pleasanton, CA 94588-0900 |
| Trade Name: Cobas AmpliScreen System |
| Cleared Date: 26-NOV-2002 |

| BK140195-0 | Roche Molecular Systems, Inc. |
| 4300 Hacienda Drive |
| Pleasanton, CA 94588-0900 |
| Trade Name: COBAS AmpliScreen Data Output Management System (DOMS) - 1.00.04 |
| Cleared Date: 10-DEC-2002 |

| BK140196-0 | Roche Molecular Systems, Inc. |
| 4300 Hacienda Drive |
| Pleasanton, CA 94588-0900 |
| Trade Name: Cobas p 680 Instrument Cobas® 8800 System |
| Cleared Date: 20-OCT-2016 |

| BK110045-0 | Rowny Systems, Inc. |
| 7555 Spring Lake Drive |
| Bethesda, MD 20817-6507 |
| Trade Name: Antigen PLUS - 7.4 |
| Cleared Date: 25-MAY-2012 |

| 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 |

| 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

BK950057-0  SG Scientific
5745 SW 75th Street
#284
Gainesville, 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
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  
Staffordshire, 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  
Staffordshire, 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  
Staffordshire, DE14 2WD United Kingdom  
Trade Name: Procleix? NAT Manager? v1.2  
Software - v1.2  
Cleared Date: 25-APR-2017

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: SCI MED UltraFuse Coron.
Infusion/Guidewire Exchange Catheter
Cleared Date: 15-MAR-1995

BK870011-0 Seabrook Medical Systems, Inc.
673 Wilmer Avenue
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

BK990018-0 Shotwell & Carr, Inc.
3555 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

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
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 21-MAR-2006
Cleared Under Bayer Healthcare Diagnostics Division

Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 19-MAR-2007

Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 20-OCT-2008

Trade Name: Promote Platelet Rich Concentrate (PRC) Preparation System
Cleared Date: 02-MAY-2006

Trade Name: Accugenics (Tray)
Cleared Date: 07-AUG-1985

Trade Name: Accugenics (HLA Control Cells)
Cleared Date: 07-AUG-1985

Trade Name: AutoFusion - v3.02
Cleared Date: 05-JUN-2009

Trade Name: SoftBank II Version 19.1
Cleared Date: 10-JUL-1998

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: Soft Donor - 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

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

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,
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

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

BK120061-0  SynGen, Inc
2125 19th Street, Suite 120
Sacramento, CA 95818
<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Clearance Date</th>
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<tbody>
<tr>
<td>SynGenX-1000</td>
<td>12-JUL-2013</td>
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<td>iTrace for Blood Centers - 1.0.924.0</td>
<td>14-SEP-2017</td>
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<td>LifeTec - 2.20</td>
<td>30-JUL-1999</td>
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<td>LifeTec Donor Verification and Collection System (DOVAC) - 1.00</td>
<td>21-OCT-2004</td>
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<td>LifeTec Elite - 1.0</td>
<td>15-AUG-2006</td>
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<td>Sysmex XE-2100D and XS-1000i</td>
<td>08-SEP-2009</td>
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<tr>
<td>Spectra Optia Apheresis System</td>
<td>25-FEB-2013</td>
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<tr>
<td>Spectra Optia Apheresis System</td>
<td>25-JUL-2013</td>
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<tr>
<td>Spectra Optia Apheresis System</td>
<td>16-JAN-2014</td>
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<tr>
<td>Trima Accel System, Version 6.2</td>
<td>19-MAR-2014</td>
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</tbody>
</table>
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

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

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.
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
Trade Name: Vista Information System, Version 3.0 with Medical Review Module
Cleared Date: 13-DEC-2007
Cleared Under Gambro BCT, Inc

Trade Name: The Atreus Whole Blood Processing System
Cleared Date: 27-JUN-2008
Cleared Under Gambro BCT, Inc

Trade Name: Trima Accel Automated Blood Component Collection System
Cleared Date: 18-MAY-2010
Cleared Under Gambro BCT, Inc

Trade Name: Vista Information System Version 3.2
Cleared Date: 01-APR-2014

Trade Name: Trima Accel System Version 6.4
Cleared Date: 29-AUG-2014

Trade Name: Model 81000 Trima Accel System Mobile Pro Package
Cleared Date: 05-NOV-2014

Trade Name: Spectra Optia Apheresis System
Cleared Date: 09-MAR-2015

Trade Name: Vista Information System - 4.0
Cleared Date: 22-SEP-2015

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

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
Rancho 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
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-OCT-1994

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

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.
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: 24-APR-2002

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

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

WHITTAKER BIOPRODUCTS, INC.
8830 Biggs Ford Road
Walkersville, MD 21793
Trade Name: ENDOTOXIN CHALLENGE VIALS
Cleared Date: 09-AUG-1991

Wako Chemicals USA, Inc.
12300 Ford Road, Suite 130
Dallas, TX 75234
Trade Name: Toxinometer ET-201
Cleared Date: 10-FEB-1987

Whitman Medical Corporation
990 Raritan Road
Clark, NJ 07066
Trade Name: Safe-T-Vue Irreversible Temperature Indicator
Cleared Date: 12-MAY-1992

Wyndgate Technologies
11121 Sun Center Drive
Suite C
Rancho Cordova, CA 95670
Trade Name: SafeTrace
Cleared Date: 14-APR-1997

Wyndgate Technologies
11060 White Rock Road
Suite 200
Rancho Cordova, CA 95670
Trade Name: SafeTrace TX, version 1.0
Cleared Date: 29-JAN-1999

Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: El Dorado Donor Doc - 1.0.0
Cleared Date: 23-MAY-2007

Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: El Dorado 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: ElDorado 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

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

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