Currently Cleared CBER 510(k)s by Applicant As of 31-DEC-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)
Trade Name: Quant-Rho FITC Anti-D for Fetal Cell Assay
Cleared Date: 27-SEP-2005
Cleared Under ALBA Bioscience

Trade Name: AlbaQ-Chek Simulated Whole Blood Controls
Cleared Date: 27-JUL-2007
Cleared Under ALBA Bioscience

Trade Name: ALBAcheck - BGS Reagent Control for Anti-D
Cleared Date: 29-JUL-2008
Cleared Under ALBA Bioscience

Trade Name: FETALSCREEN
Cleared Date: 08-APR-2009
Cleared Under ALBA Bioscience

Trade Name: ALBAcheck- BGS Whole Blood Controls-SP
Cleared Date: 14-JUN-2010
Cleared Under ALBA Bioscience

Trade Name: ALBAcyte IgG Sensitized Red Blood Cells
Cleared Date: 26-AUG-2010
Cleared Under ALBA Bioscience

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-Biomedical 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
<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Cleared Date</th>
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<tbody>
<tr>
<td>Alliance Partners LLC</td>
<td>14206 Northbrook Drive San Antonio, TX 78232</td>
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<tr>
<td>Cyclone Blood &amp; Bone Marrow Concentration (BBMC) System</td>
<td>02-JAN-2018</td>
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<tr>
<td>Alliance Technologies, LLC</td>
<td>1552 West Griswold Rd Phoenix, AZ 85021</td>
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<tr>
<td>BloodRelay 1.0.0</td>
<td>17-SEP-2019</td>
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<tr>
<td>Alpha Scientific Corporation</td>
<td>725 Southeastern, PA 19399</td>
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<tr>
<td>SEG-Safe (TM)</td>
<td>15-MAR-1995</td>
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<tr>
<td>Alpha Scientific Corporation</td>
<td>725 Southeastern, PA 19399</td>
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<tr>
<td>SEG-SAFE</td>
<td>31-MAR-1995</td>
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<tr>
<td>Alpha Therapeutic Corporation</td>
<td>5555 Valley Boulevard Los Angeles, CA 90032</td>
</tr>
<tr>
<td>JMS Double Blood Collection Pack</td>
<td>04-JUN-1986</td>
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<tr>
<td>Alpha Therapeutic Corporation</td>
<td>5555 Valley Boulevard Los Angeles, CA 90032</td>
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<tr>
<td>Plasma Transfer Pack</td>
<td>11-MAR-1987</td>
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<tr>
<td>Alpha Therapeutic Corporation</td>
<td>13111 Temple Avenue City of Industry, CA 91746</td>
</tr>
<tr>
<td>Transfer Device</td>
<td>18-OCT-1995</td>
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<tr>
<td>Alton Dean Medical, Inc.</td>
<td>1547 West 2290 South Woods Cross, UT 84087</td>
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<tr>
<td>Alton Dean Model FW-437</td>
<td>15-MAY-1995</td>
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<tr>
<td>American Blood Resources Association</td>
<td>PO Box 669 Annapolis, MD 21404</td>
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<tr>
<td>National Donor Deferral Registry</td>
<td>20-MAR-1997</td>
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<tr>
<td>American Blood Resources Association</td>
<td>147 Old Solomons Island Rd. Annapolis, MD 21401</td>
</tr>
<tr>
<td>National Donor Deferral Registry (NDDR) - 1.0</td>
<td>06-SEP-2001</td>
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</table>
American Red Cross
Diagnostic Manufacturing Division
2025 E Street NW
Washington, DC 20006
Trade Name: NBCS 1.1
Cleared Date: 28-FEB-1997

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

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

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

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

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

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

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

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

Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name: Bovine Albumin 22%
BK860003-0  Amtec Diagnostics International Inc.  
1107 IH-45 South  
Conroe, TX 77305  
Trade Name: Bovine Albumin 30%  
Cleared Date: 03-MAR-1986

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

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

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

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

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

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

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

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

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

BK030005-0  Applied Biosystems  
1401 Harbor Bay Parkway  
Alameda, CA 94502
BK170144-0 Arthrex, Inc.
1370 Creekside Boulevard
Naples, FL 34108
Trade Name: Arthrex Thrombinator™ System
Thrombinator™ System for use with the Arthrex Angel concentrated Platelet Rich Plasma (PRP) System
Cleared Date: 10-MAY-2018

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

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

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

BK190406-0 Arthrex, Inc.
1370 Creekside Boulevard
Naples, FL 34108
Trade Name: Arthrex Double Syringe (ACP) System
Cleared Date: 06-NOV-2019

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 70th 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
West Bridgewater, MA 02379
Trade Name: ACCURUN 365 West Nile Virus RNA Positive Quality Control
Cleared Date: 12-JUN-2006

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

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

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

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

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

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

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

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

BK980011-0  BECTON DICKINSON VACUTAINER Systems
1 Becton Drive
Franklin Lakes, NJ 07417
Trade Name: VACUTAINER Brand PLUS (Plastic) Blood Collection Tube with EDTA Anticoagulant
Cleared Date: 07-JUN-1999
BMT Incorporated
7315 Hazeltine Boulevard
Excelsior, MN 55331
Trade Name: BMT Model 24 Bloodmixer
Cleared Date: 22-OCT-1982

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

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

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

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

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

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

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

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

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

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

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

BK020059-0  Baxter Healthcare Corporation  
25212 West ILL Route 120  
Round Lake, IL 60073  
Trade Name: ALYX Component Collection System  
Clear 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  
Clear Date: 24- JUL-2017

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

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

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

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

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

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

Trade Name: stemCXP System for the FC 500 with CXP Software
Cleared Date: 16-SEP-2004

Trade Name: HLA-B27 Screening Systems
Cleared Date: 09-SEP-1993

Trade Name: The HLA-B27 System
Cleared Date: 24-OCT-1994

Trade Name: ProCount Progenitor Cell Enumeration Kit
Cleared Date: 04-JUN-1998

Trade Name: Procount Software
Cleared Date: 04-FEB-1999

Trade Name: LeucoCOUNT Reagent
Cleared Date: 14-AUG-1998

Trade Name: CMV Scan Card Test
Cleared Date: 22-DEC-1995

Trade Name: BD Vacutainer Plus Plastic Serum Tubes with Clot Activator
Cleared Date: 05-MAY-2004

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 Loveton Circle, MC 694
Sparks, MD 21152-0999
Trade Name: BD BACTEC™ Platelet Aerobic/F Culture Vials
BD BACTEC™ Platelet Anaerobic/F Culture Vials
Cleared Date: 08-AUG-2018

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

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

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

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

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

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

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

BK180175-0 Bio-Rad Medical Diagnostics GmbH
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) v6.0
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) v1.0
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 Concentration Separation Kit
Cleared Date: 18-JUN-2004
Cleared Under Biomet, Inc.

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

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

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

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

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

BK090008-0 Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name: MarrowStim Concentration System
Cleared Date: 18-DEC-2009
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 Mi nano (Alava)
Alava, Spain 01510
Trade Name: Endoret Kit
Secondary Product Code: FMI, GKT
Cleared Date: 01-FEB-2010

BK060066-0 Biotest AG
Postfach 10 20 40
D-63266 Dreiech, Germany
Trade Name: TANGO Automated Blood Bank Analyzer System, Version 3.0 Service Pack 4
Cleared Date: 17-JAN-2007

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

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

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

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

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

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

BK020004-0 Biotest Diagnostics Corporation
66 Ford Road, Suite 131
<table>
<thead>
<tr>
<th>Registration Number</th>
<th>Company Name</th>
<th>Address</th>
<th>Trade Name</th>
<th>Clear Date</th>
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</thead>
<tbody>
<tr>
<td>BK920008-0</td>
<td>Blackhawk BioSystems, Inc.</td>
<td>12945 Alcosta Blvd., San Ramon, CA 94583</td>
<td>VIROTROL</td>
<td>17-SEP-1992</td>
</tr>
<tr>
<td>BK920028-0</td>
<td>Blackhawk BioSystems, Inc.</td>
<td>12945 Alcosta Blvd., San Ramon, CA 94583</td>
<td>Virotrol HIV-2</td>
<td>03-JUN-1993</td>
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<tr>
<td>BK930016-0</td>
<td>Blackhawk BioSystems, Inc.</td>
<td>12945 Alcosta Blvd., San Ramon, CA 94583</td>
<td>Virotrol I Reagents (CMV)</td>
<td>16-NOV-1993</td>
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<tr>
<td>BK930033-0</td>
<td>Blackhawk BioSystems, Inc.</td>
<td>12945 Alcosta Blvd., San Ramon, CA 94583</td>
<td>Virotrol HIV-Ag</td>
<td>27-SEP-1995</td>
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<td>BK930034-0</td>
<td>Blackhawk BioSystems, Inc.</td>
<td>12945 Alcosta Blvd., San Ramon, CA 94583</td>
<td>Virotrol III</td>
<td>27-JUL-1994</td>
</tr>
<tr>
<td>BK950011-0</td>
<td>Blackhawk BioSystems, Inc.</td>
<td>12945 Alcosta Blvd., San Ramon, CA 94583</td>
<td>Viroclear</td>
<td>28-AUG-1995</td>
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<tr>
<td>BK960085-0</td>
<td>Blackhawk BioSystems, Inc.</td>
<td>12945 Alcosta Blvd., San Ramon, CA 94583</td>
<td>VIROTROL II</td>
<td>03-OCT-1997</td>
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<tr>
<td>BK000041-0</td>
<td>Blackhawk BioSystems, Inc.</td>
<td>12945 Alcosta Blvd., San Ramon, CA 94583</td>
<td>Viroclear</td>
<td>28-DEC-2000</td>
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<tr>
<td>BK060052-0</td>
<td>Blackhawk BioSystems, Inc.</td>
<td>12945 Alcosta Blvd., San Ramon, CA 94583</td>
<td>AmpliTrol III</td>
<td>07-NOV-2006</td>
</tr>
<tr>
<td>BK040056-0</td>
<td>Blood Bank Computer Systems, Inc.</td>
<td>1002 15th St. SW, Suite 120, Auburn, WA 98001-6502</td>
<td>Blood Bank Control System (BBCS)</td>
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</tr>
</tbody>
</table>
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

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

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

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

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

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

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

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

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

Blood Care
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.
Mequon, WI 53092
Trade Name: Frozen Cell Panel Tray (Human)
Cleared Date: 02-AUG-1989

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

BK890011-0 C-six Diagnostics, Inc.
9653 N. Granville Rd.
Mequon, 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 Spectra LRD Leukoreduction (System Versions)
Cleared Date: 31-JAN-1996
Cleared Under COBE BCT

BK950065-0 COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name: Cobe Spectrum Apheresis System (stem cell collection)
Cleared Date: 12-NOV-2002
Cleared Under COBE BCT
BK960076-0  COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name: COBE Spectra LRS Turbo System
Cleared Date: 14-JUL-1997
Cleared Under COBE BCT

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

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

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

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

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

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

BK060010-0  COBE Cardiovascular, Inc.
14401 West 65th Way
Arvada, CO 80004-3599
Trade Name: COBE Angel Whole Blood Separation System
Cleared Date: 27-FEB-2006

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

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

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

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

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

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

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

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

BK940027-0 Cardiovascular Dynamics, Inc.
15 Hammond Suite 307
Irvine, CA 92718
Trade Name: CVD Bullet Infusion Catheter
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

B080035-0 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

B080043-0 CaridianBCT  
10811 W. Collins Avenue  
Lakewood, CO 80215-4498  
Trade Name: Atreus Whole Blood Processing System  
Cleared Date: 29-SEP-2008

B080058-0 CaridianBCT  
10811 W. Collins Avenue  
Lakewood, CO 80215-4498  
Trade Name: Trima Accel Automated Blood Component Collection System  
Cleared Date: 25-NOV-2008

B090003-0 CaridianBCT  
10811 W. Collins Avenue  
Lakewood, CO 80215-4498  
Trade Name: Trima Accel System  
Cleared Date: 16-FEB-2010

B100032-0 CaridianBCT  
10811 W. Collins Avenue  
Lakewood, CO 80215-4498  
Trade Name: Trima Accel System Version 6.0  
Cleared Date: 06-AUG-2010

B110009-0 CaridianBCT  
10811 W. Collins Avenue  
Lakewood, CO 80215-4498  
Trade Name: Trima Accel Automated Blood Component Collection System  
Cleared Date: 19-APR-2011

B110051-0 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

B110068-0 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 FIBRINET System
Cleared Date: 16-FEB-2006

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

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

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

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

BK060049-0  Celera Corporation
1401 Harbor Bay Parkway
Alameda, CA 94502
Trade Name: ViroSeq HIV-1 Genotyping System
Cleared Date: 31-AUG-2006
Cleared Under Celera Diagnostics, LLC

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK050021-0 Charter Medical, Ltd.
3948-A Westpoint Blvd.
Winston-Salem, NC 27103
Trade Name: Charter Medical Transfer Set
Cleared Date: 22-JUL-2005

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

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

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

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

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

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

BK910020-0 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name: COBE SPECTRATHERM
Cleared Date: 02-NOV-1992

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

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

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

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

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

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

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

BK110048-0 Community Blood Centers of South Florida
1700 North State Road 7
Lauderhill, FL 33313
Trade Name: Regulated Software Application (RSA) - 1.0
Cleared Date: 12-JAN-2012

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

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

BK940026-0 Cook, Inc.
925 S. Curry Pike
Bloomington, IN 47402
Trade Name: Roubin Infusion Catheter
Cleared Date: 29-JUN-1995
BK830008-0  Cooper Biomedical  
1230 Wilson Drive  
West Chester, PA 19380  
Trade Name: W.A.R.M.  
Cleared Date: 21-JUN-1983

BK850008-0  Cooper Biomedical  
1 Technology Court  
Malvern, PA 29335  
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: Cyto Therm (T-S)
Cleared Date: 15-APR-1996
Cleared Under Photo-Therm

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

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

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

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

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

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

BK130060-0  Cytonics Corporation
555 Heritage Drive, Suite 115
Jupiter, FL 33458
Trade Name: Autologous Platelet Integrated Concentration ("API C") 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
BK00022-0  DENCO, INC.
P.O. BOX 9600
Wilmington, DE 19809
Trade Name: Total Containment Device
Cleared Date: 18-APR-2000

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

BK160084-0  DIAGAST
Parc Eurasanté
251, Avenue Eugène 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 - 8.10.01  
Cleared Date: 12-AUG-2010  
Cleared Under Data Innovations Inc.

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

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

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

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

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
<table>
<thead>
<tr>
<th>Product Code</th>
<th>Company</th>
<th>Address</th>
<th>City, State, Zip Code</th>
<th>Trade Name</th>
<th>cleared Date</th>
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<tr>
<td>BK830025-0</td>
<td>Dia Tech</td>
<td>2525 Shader Road</td>
<td>Orlando, FL 328</td>
<td>DiaCent 2 Automated Cell Washer/Centrifuge</td>
<td>10-JAN-1984</td>
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<td>BK840001-0</td>
<td>Dia Tech</td>
<td>2525 Shader Road</td>
<td>Orlando, FL 328</td>
<td>DIACENT 1, Automated Cell Washer/Centrifuge</td>
<td>19-MAR-1984</td>
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<td>BK870007-0</td>
<td>DiaClin Laboratories, Inc.</td>
<td>450 10th Circle North</td>
<td>Nashville, TN 37203</td>
<td>SEOPF ROP Tray</td>
<td>04-APR-1990</td>
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<td>BK120043-0</td>
<td>Diagnostic Grifols, S. A.</td>
<td>Passeig Fluvial, 24</td>
<td>Barcelona, Parets Del Valles, Spain 08150</td>
<td>DG Gel 8 Neutral Gel</td>
<td>19-JUL-2013</td>
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<td>BK120044-0</td>
<td>Diagnostic Grifols, S. A.</td>
<td>Passeig Fluvial, 24</td>
<td>Barcelona, Parets Del Valles, Spain 08150</td>
<td>Grifols Diluent</td>
<td>19-JUL-2013</td>
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<td>BK120045-0</td>
<td>Diagnostic Grifols, S. A.</td>
<td>Passeig Fluvial, 24</td>
<td>Barcelona, Parets Del Valles, Spain 08150</td>
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<td>19-JUL-2013</td>
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<td>BK120046-0</td>
<td>Diagnostic Grifols, S. A.</td>
<td>Passeig Fluvial, 24</td>
<td>Barcelona, Parets Del Valles, Spain 08150</td>
<td>DG THERM</td>
<td>19-JUL-2013</td>
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<td>BK130025-0</td>
<td>Diagnostic Grifols, S. A.</td>
<td>Passeig Fluvial, 24</td>
<td>Barcelona, Parets Del Valles, Spain 08150</td>
<td>WADiana(R) Compact</td>
<td>30-AUG-2013</td>
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<td>BK130067-0</td>
<td>Diagnostic Grifols, S. A.</td>
<td>Passeig Fluvial, 24</td>
<td>Barcelona, Parets Del Valles, Spain 08150</td>
<td>Erytra(R)</td>
<td>17-JAN-2014</td>
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BK140101-0  Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, Spain 08150
Trade Name: DG Reader
Cleared Date: 21-MAY-2014

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

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

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

BK180260-0  Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, Spain 08150
Trade Name: Erytra Eflexis
Cleared Date: 20-DEC-2018

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

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

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

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

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

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

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

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

BK000020-0 Digi-Trax Corporation
1550 Barclay Boulevard
Buffalo Grove, IL 60089
Trade Name: Digi-Trax Donor-ID - 2.0
Cleared Date: 20-APR-2000

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

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

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

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

BK090079-0 Duley Hopkins and Associates
1200 Mountain Creek Road
# 215
Chattanooga, TN 37405
Trade Name: Blood Bank Information Management System (BBIMS V2.05.01)
Cleared Date: 13-JAN-2010
BK030056-0 Dynal Biotech Ltd
11 Bassendale Road
Croft Business Park
Bromborough, Wirral, CH62 3QL, United Kingdom
Trade Name: Dynal RELI SSO HLA-A Typing Kit
Cleared Date: 29-JAN-2004

BK030057-0 Dynal Biotech Ltd
11 Bassendale Road
Croft Business Park
Bromborough, Wirral, CH62 3QL, United Kingdom
Trade Name: Dynal RELI SSO HLA-B Typing Kit
Cleared Date: 29-JAN-2004

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

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

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

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

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

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

BK850013-0 Dynatech Laboratories, Inc.
900 Slaters Lane
Alexandria, VA 22314
Trade Name: MicroBank System
Cleared Date: 08-OCT-1985

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

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

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 cm 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 (mononeuclear cells)
Cleared Date: 12-NOV-2002
Cleared Under Baxter Healthcare Corporation

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

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

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

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

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

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

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

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

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

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

BK020008-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: LeukoConnect - Pre-Storage Sterile Connect Leukoreduction Set with Sepacell Filter for Red Blood
Cells
Cleared Date: 10-DEC-2002
Cleared Under Baxter Healthcare Corporation - I.V. Systems Division

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

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

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

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

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

BK050038-0  Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: AMICUS Separator System
Cleared Date: 03-NOV-2005
Cleared Under Baxter Healthcare Corporation

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

BK080024-0  Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: ALYX Component Collection System
Cleared Date: 24-JUN-2008
BK080048-0  Fenwal Inc
  Three Corporate Drive
  2nd Floor
  Lake Zurich, IL 60047
  Trade Name: AMICUS Separator
  Cleared Date: 02-OCT-2008

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

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

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

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

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

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

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

BK110025-0  Fenwal Inc
  Three Corporate Drive
  2nd Floor
  Lake Zurich, IL 60047
  Trade Name: Software, Blood Ban, Stand Alone
BK110030-0  Fenwal Inc  
Three Corporate Drive  
2nd Floor  
Lake Zurich, IL 60047  
Trade Name: AMICUS Separator System with Software Version 4.3  
Cleared Date: 23-DEC-2011

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

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

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

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

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

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

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

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

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

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

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

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

BK120047-0 Fenwal, Inc.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Autopheresis-C Plasmapheresis System
Plasmacell-C Set
Cleared Date: 18-DEC-2012

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

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

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

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

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

BK160012-0 Fresenius Kabi AG  
Else-Kroner-Strasse 1  
Bad Homburg, Germany 61346  
Trade Name: Aurora Plasmapheresis System, Software Version 1.3  
Cleared Date: 19-MAY-2016

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

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

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

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

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

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

BK180293-0 Fresenius Kabi AG
Three Corporate Dr
Lake Zurich, IL 60047
Trade Name: Plasmalink Bottle with Locking Luer Adapter
Cleared Date: 21-DEC-2018

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

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

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
Refurbished
Cleared Date: 10-OCT-2017

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

BK030022-0 Fresenius Medical Care North America
6675 185th Avenue NE
Suite 100
Redmond, WA 98052
Trade Name: Fresenius Compomat G4 & Compomaster NT
Cleared Date: 11-JUL-2003
Cleared Under Fresenius Hemocare Inc.

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

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

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

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

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

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

BK960070-0 Fujirebio Diagnostics, Inc.
201 Great Valley Parkway
Malvern, PA 19355
Trade Name: Olympus PK-TP System Control Set
Cleared Date: 19-JUN-1997
Cleared Under SCI MEDX Corporation

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

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

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

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

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

BK940055-0 Futuremed
2076 Deer Park Avenue
Deer Park, NY 11729
Trade Name: L Fusion Bags for Warming
Blood/Plasma w/ ANIMEC4
Cleared Date: 27-DEC-1994

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

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

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

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

BK830014-0  Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Elu-Kit II
Cleared Date: 25-NOV-1983

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

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

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

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

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

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

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

BK850021-0  Gamma Biologicals, Inc.
3700 Mangum Road
Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma Micro-U Accessory Equipment
Cleared Date: 20-MAR-1986

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

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

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

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

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

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

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

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

BK960090-0  Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma EGA Kit
Cleared Date: 21-JUL-1997

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

BK970003-0  Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma-ReACT Reader
Cleared Date: 30-MAY-1997

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

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

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

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

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

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

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

BK050007-0  Gen-Probe
10210 Genetic Center Drive
San Diego, CA 92121-4362
Trade Name: Procleix System
Cleared Date: 29-APR-2005

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

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

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

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

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

BK040019-0  Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: Antibody Monitoring System Class I and Class II (AMS1 and AMS1+2)
Cleared Date: 06-JUL-2004
Cleared Under GTI, INC

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

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

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

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

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

BK070034-0  Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: HLA EZ Type
Cleared Date: 10-JUL-2008
Cleared Under GTI, INC
BK070045-0  Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: Donor Screen HLA Class I and Class II
Cleared Date: 30-JUL-2008
Cleared Under GTI, INC

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

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 DENO, 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
<table>
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<tr>
<th>Trade Name</th>
<th>Cleared Date</th>
<th>Location</th>
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<tbody>
<tr>
<td><strong>GTI-60 HLA Typing Trays</strong></td>
<td>24-FEB-1987</td>
<td>Milwaukee, WI 53233</td>
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<td><strong>GTI-72 HLA Typing Trays</strong></td>
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<td><strong>GTI-96 HLA Typing Trays</strong></td>
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<td><strong>GTI Pep Antibody Enhancement Solution</strong></td>
<td>23-JUN-1992</td>
<td>Milwaukee, WI 53233</td>
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<td><strong>GTI Reduced Wash Elution Kit</strong></td>
<td>28-OCT-1993</td>
<td>Milwaukee, WI 53233</td>
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<td><strong>GTI ACE Antigen Capture ELISA for Detection of IgG Antibodies to Platelet Specific Antibodies</strong></td>
<td>20-JUN-1994</td>
<td>Milwaukee, WI 53233</td>
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<td><strong>GTI-PAK 2 Platelet Antibody Screening Kit</strong></td>
<td>15-MAY-1995</td>
<td>Milwaukee, WI 53233</td>
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<td><strong>GTI-HLA 1, Class I Antibody Screening Kit</strong></td>
<td>19-MAY-1995</td>
<td>Milwaukee, WI 53233</td>
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<td><strong>GTI-HAT, Heparin-Associated Antibody Screening Kit</strong></td>
<td>14-APR-1997</td>
<td>Milwaukee, WI 53233</td>
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<td><strong>GTI PAT HPA-1 (Pl) Genotyping Kit</strong></td>
<td>23-APR-1999</td>
<td>Brookfield, WI 53045</td>
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<tr>
<td><strong>Quick ID Solid Phase ELISA for detection of Panel Reactive HLA Class I IgG Antibodies (PRA)</strong></td>
<td>17-OCT-2000</td>
<td>Brookfield, WI 53045</td>
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<tr>
<td><strong>GTI PAT HPA-1 (PI) Genotyping Kit</strong></td>
<td>23-APR-1999</td>
<td>Brookfield, WI 53045</td>
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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
Cleared Under sienna partners

BK140150-0 Grifols Diagnostic Solutions Inc.
4560 Horton Street, M/S N-200
Emeryville, CA 94608-2916
Trade Name: Procleix Xpress® System
Cleared Date: 27-AUG-2014

BK170162-0 Grifols Diagnostic Solutions Inc.
4560 Horton Street, M/S N-200
Emeryville, CA 94608-2916
Trade Name: Procleix Xpress® System (Software v3.0)
Cleared Date: 18-JAN-2018

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

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

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

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

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

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

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

BK870026-0  Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics Ultralite Plasma Collection System  
Cleared Date: 17-MAR-1988

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

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

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

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

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

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

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

BK930007-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: 790 Extended Storage Platelet Collection Set
(Cleared Date: 16-NOV-1993)

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

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

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

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

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

BK950006-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: List #890F Extended Storage Plt Collection Set
(Cleared Date: 09-JUN-1995)
Trade Name: ESP White Cell Filter (No. 790F) 
Cleared Date: 28-JUN-1995

Trade Name: Haemonetics PCS2 
Cleared Date: 16-APR-1996

Trade Name: Double Product Collection (SDP-3) 
Cleared Date: 15-FEB-1996

Trade Name: Red Blood Cell and Plasma Collection Set for the MCS Plus #823 
Cleared Date: 22-JUL-1996

Trade Name: Double Unit Red Blood Cell Apheresis Set MCS #833 
Cleared Date: 15-OCT-1996

Trade Name: MCS+Double Unit RBC Apheresis Set-Dry (LN832) 
Cleared Date: 16-APR-1997

Trade Name: MCS+Red Cell & Plasma Apheresis Set - Dry (LN822) 
Cleared Date: 16-APR-1997

Trade Name: MCS+Apheresis System (LN8150) 
Cleared Date: 11-APR-1997

Trade Name: Alpha Plasma Pooling Bottle II (60-2227S) 
Cleared Date: 07-JAN-1998 
Cleared Under Alpha Therapeutic Corporation

Trade Name: LN994CF
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

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

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

BK990044-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics LN832F Two Unit Red Cells Disposable Set with Leukocyte reduction Filter
Cleared Date: 27-OCT-2000

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

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

BK020001-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Plasma Pooling Bottle II
Cleared Date: 29-MAR-2002

BK030031-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics Model 215 Automated Glycerolization / Deglycerolization and Cell Washing System
Cleared Date: 10-SEP-2003

BK030062-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics Model 215 Automated Glycerolization/deglycerolization System
Cleared Date: 10-DEC-2003

BK030084-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics LN994CF-CPP-BA Extended Storage Platelet and Plasma Apheresis Set
Cleared Date: 09-JAN-2004

BK040001-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics 4mL Sampling System
Cleared Date: 27-FEB-2004

BK040020-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics LN994CF-BA Extended Storage Platelet and Plasma Apheresis Set with Leukocyte Reduction Filter, and 4 mL Sampling System.
Cleared Date: 29-MAR-2004

BK040025-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: PCS2 Plasma Collection System
Cleared Date: 02-JUN-2004

BK040041-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics MCS+8150 Apheresis System
Cleared Date: 12-JUL-2004

BK040077-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics Model 215 Automated Glycerolization/Deglycerolization System
Cleared Date: 21-DEC-2004

BK050006-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: ACP 215 Glycerolization/Deglycerolization System
Cleared Date: 14-APR-2005

BK050047-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114

Trade Name: MCS+9000, SDP revision E software, 994CF-CPP series disposable sets
Cleared Date: 21-NOV-2005

BK050048-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics MCS+8150 Apheresis System
Cleared Date: 27-SEP-2005

BK060008-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics ACP 215 Glycerolization/Deglycerolization System
Cleared Date: 23-MAY-2006

BK060023-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics MCS+8150 Apheresis System
Cleared Date: 23-MAY-2006

BK060033-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics PCS 2 Plasma Collection System, Wireless (W) Capable Modification
Cleared Date: 27-MAR-2008

BK060057-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Cymbal Automated Blood Collection System
Cleared Date: 28-FEB-2007

BK070019-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics PCS2 Plasma Collection System
Cleared Date: 23-MAY-2007

BK080025-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Cymbal Automated Blood Collection System
Cleared Date: 15-AUG-2008

BK090041-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Symphony System
Cleared Date: 28-SEP-2009

BK090083-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Cymbal Automated Blood Collection System
Cleared Date: 27-JAN-2010

BK110015-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: NextGen - 1.0.0
Cleared Date: 13-JUN-2011

BK120065-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: PCS2 Plasma Collection System
Cleared Date: 26-NOV-2012

BK120083-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: MCS+ 8150 System - Wireless
Cleared Date: 20-MAR-2013

BK120084-0 Haemonetics Corporation
4925 Robert J Mathews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: Phlebotomy System
Cleared Date: 30-APR-2013

BK130056-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics PCS2 Plasma Collection System
Cleared Date: 29-AUG-2014

BK130081-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Cymbal Automated Blood Collection System
Cleared Date: 23-JAN-2014

BK130082-0 Haemonetics Corporation
4925 Robert J Mathews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: NextGen
Cleared Date: 08-AUG-2014

BK140108-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: MCS+ 8150
Cleared Date: 26-AUG-2014

BK140199-0 Haemonetics Corporation
4925 Robert J Mathews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: Surround 5.1
Cleared Date: 05-FEB-2015

BK150287-0 Haemonetics Corporation
400 Wood Road
Cleared Date: 04-SEP-2008
Cleared Under Haemonetics Corporation

BK090004-0 Haemonetics Corporation Software Solutions
1630 Industrial Park Street
Covina, CA 91722-9144
Trade Name: MCS+B150 System - Wireless
Cleared Date: 20-FEB-2009
Cleared Under Haemonetics Corporation

BK140133-0 Haemonetics Corporation Software Solutions
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: BloodTrack - 4.7.0
Cleared Date: 29-AUG-2014

BK140166-0 Haemonetics Corporation Software Solutions
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: Cross Donation Check System (CDCS) - 1.0.0
Cleared Date: 10-OCT-2014

BK140183-0 Haemonetics Corporation Software Solutions
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: Donor Doc 3.0.0
Cleared Date: 10-DEC-2014

BK150308-0 Haemonetics Corporation Software Solutions
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: 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.
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<th>Trade Name</th>
<th>Cleared Date</th>
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<tr>
<td>BK020014-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road, Braintree, MA 02184</td>
<td>Pall Bacterial Detection System (BDS)</td>
<td>22-OCT-2002</td>
<td>Medsep Corporation</td>
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<td>BK030082-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road, Braintree, MA 02184</td>
<td>Pall eBDS</td>
<td>04-FEB-2004</td>
<td>Medsep Corporation</td>
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<td>BK050015-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road, Braintree, MA 02184</td>
<td>Leukotrap SC RC Filtration System</td>
<td>14-APR-2005</td>
<td>MEDSEP Corp.</td>
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<td>BK050034-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road, Braintree, MA 02184</td>
<td>Pall Acrodose PL System, Platelet Pool and Store Set with eBDS with Pall eBDS</td>
<td>28-SEP-2005</td>
<td>Medsep Corporation</td>
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<td>BK050074-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road, Braintree, MA 02184</td>
<td>Pall Acrodose PL System</td>
<td>26-JAN-2006</td>
<td>Medsep Corporation</td>
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<td>BK050075-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road, Braintree, MA 02184</td>
<td>Pall eBDS</td>
<td>20-DEC-2005</td>
<td>Medsep Corporation</td>
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<td>BK060040-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road, Braintree, MA 02184</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>
</tr>
<tr>
<td>BK060044-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road, Braintree, MA 02184</td>
<td>Pall Acrodose PL System, Platelet Pool and Store Set with eBDS</td>
<td>01-SEP-2006</td>
<td>Medsep Corporation</td>
</tr>
<tr>
<td>BK060045-0</td>
<td>Haemonetics Manufacturing Inc.</td>
<td>400 Wood Road, Braintree, MA 02184</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
BK060047-0  Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall eBDS  
Cleared Date: 04-APR-2007  
Cleared Under Medsep Corporation

BK070004-0  Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall eBDS  
Cleared Date: 26-JUN-2007  
Cleared Under Medsep Corporation

BK070056-0  Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall Acrodose PLus System Platelet Pool and Store Set with in-line Leukocyte Reduction Filter and eBDS  
Cleared Date: 27-SEP-2007  
Cleared Under Medsep Corporation

BK070057-0  Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall Acrodose PLus System Platelet Pool and Store Set with in-line Leukocyte Reduction Filter  
Cleared Date: 27-SEP-2007  
Cleared Under Medsep Corporation

BK070063-0  Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall eBDS  
Cleared Date: 26-JAN-2008  
Cleared Under Medsep Corporation

BK080003-0  Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall Acrodose PLus System, Platelet Pool and Store Set with in-Line Leukocyte Reduction Filter  
Cleared Date: 18-APR-2008  
Cleared Under MEDSEP Corporation

BK090007-0  Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall Acrodose PL System  
Cleared Date: 25-FEB-2009  
Cleared Under Medsep Corporation

BK160027-0  Haemonetics Manufacturing Inc.  
1630 Industrial Park Street
Covina, CA 91722
Trade Name: Acrodose PL System
Cleared Date: 16-MAY-2016

BK000037-0 Harvest Technologies
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 System
Cleared Date: 20-NOV-2018

BK050001-0 Healthcare Management Systems, Inc.
3102 West End Avenue, Suite 400
Nashville, TN 37203
Trade Name: Monitor Blood Administration Module - Release 24.0
Cleared Date: 28-SEP-2005

BK090025-0 Healthcare Management Systems, Inc.
3102 West End Avenue, Suite 400
Nashville, TN 37203
Trade Name: HMS Blood Administration Module, Release 8.0
Cleared Date: 04-MAR-2010

BK030049-0 Healthcare-ID, Inc.
1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name: Donor-ID - version 2.5
Cleared Date: 31-OCT-2003
Cleared Under Healthcare-ID

BK060058-0 Healthcare-ID, Inc.
1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name: Donor-ID - 3.0
Cleared Date: 08-FEB-2007
Cleared Under Healthcare-ID
BK080044-0  Healthcare-ID, Inc.
1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name: Donor-ID Web - 3.1.4
Cleared Date: 10-JUN-2009
Cleared Under Healthcare-ID

BK120030-0  Healthcare-ID, Inc.
1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name: Donor-ID Web (TM) 3.2
Cleared Date: 25-JUN-2012
Cleared Under Healthcare-ID

BK140149-0  Healthcare-ID, Inc.
1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name: Donor-ID TM version 3.2.6
Cleared Date: 23-JAN-2015

BK150279-0  Healthcare-ID, Inc.
1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name: Donor-ID 3.2 integrated with iCAS\textregistered 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\textregistered App Android
Cleared Date: 29-JUL-2016

BK170141-0  Helmer Inc.
14400 Bergen Blvd
Noblesville, IN 46060
Trade Name: UltraCW
UltraCW\textregistered 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
Cleared Date: 30-AUG-1985

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

Cleared Date: 21-OCT-1985

Helmer Labs., Inc.  
5415 Distribution Drive  
Fort Wayne, IN 46825  
Trade Name: Tube Stripper  
Cleared Date: 03-MAR-1995

Helmer Labs., Inc.  
15425 Herriman Boulevard  
Noblesville, IN 46060  
Trade Name: UltraCW (with Software version 3.13)  
Cleared Date: 04-OCT-2002

Hemagen Diagnostics, Inc.  
9033 Red Branch Road  
Columbia, MD 21045  
Trade Name: Olympus PK CMV System  
Cleared Date: 11-DEC-1989

Hemagen Diagnostics, Inc.  
9033 Red Branch Road  
Columbia, MD 21045  
Trade Name: Olympus PK TM CMV System & System Controls  
Cleared Date: 15-JUL-1996

Hemasoft Software SL  
Antonio Lopez 249, 4 3A  
Madrid, Spain 28041  
Trade Name: e-Dolphyn Blood management Software version 7.1.0.0  
Cleared Date: 24-OCT-2015

Hemasure, Inc.  
140 Locke Drive  
Marlborough, MA 01752  
Trade Name: LeukoNet Pre Storage Leukodepletion Filtration System  
Cleared Date: 28-JUN-1995

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: HemoQC
Cleared Date: 08-SEP-2014

BK160079-0 Hemo bioscience
633 Davis Drive
Suite 100
Morrisville, NC 27560
Trade Name: MQC
Cleared Date: 27-FEB-2017

BK160081-0 Hemo bioscience
633 Davis Drive
Suite 100
Morrisville, NC 27560
Trade Name: MQC-CAT
Cleared Date: 30-MAR-2017

BK060020-0 HemoCue AB
40 Empire Drive
Lake Forest, CA 92630
Trade Name: HemoCue Hb 301 System
Cleared Date: 14-APR-2006

BK060048-0 HemoCue AB
Kuvettgatan 1
Angelholm, Sweden SE-262 71
Trade Name: HemoCue Hb 301 System
Cleared Date: 05-OCT-2006

BK000043-0 HemoCue, Incorporated
9229 Cranford Drive
Potomac, MD 20854
Trade Name: HemoCue Low Hemoglobin Analyzing System
Cleared Date: 09-APR-2001
BK030020-0  HemoCue, Incorporated  
9229 Cranford Drive  
Potomac, MD 20854  
Trade Name: Donor Hemoglobin Checker System  
Cleared Date: 17-APR-2003

BK030067-0  HemoCue, Incorporated  
9229 Cranford Drive  
Potomac, MD 20854  
Trade Name: HemoCue Donor Hb Checker Control  
Cleared Date: 19-DEC-2003

BK040031-0  Hemosystem, S.A.  
45, Cours Gouffe  
13006 Marseille, France  
Trade Name: Scansystem bacterial detection device  
Cleared Date: 23-SEP-2004

BK900024-0  Heraeus Inc.  
111A Corporate Blvd, S.  
Plainfield, NJ 07080  
Trade Name: Cryofuge 6000  
Cleared Date: 05-NOV-1992

BK900015-0  I. B. G. Systems Inc.  
P.O. Box 5306  
Laytonsville, MD 20882  
Trade Name: Inverness Blood Grouping System  
Cleared Date: 20-SEP-1990

BK920019-0  I. B. G. Systems Inc.  
P.O. Box 5306  
Laytonsville, MD 20882  
Trade Name: Inverness Automated Antibody Screening System  
Cleared Date: 26-MAR-1993

BK930025-0  ICU MEDICAL INC  
142 TECHNOLOGY DRIVE  
IRVINE, CA 92718  
Trade Name: Kelsea Clamp Needle Cover & Guide  
Cleared Date: 28-OCT-1993

BK110064-0  IT Synergistics, LLC  
115 Tree Street  
Flowood, MS 39232  
Trade Name: DoVac Elite 1.0  
Cleared Date: 06-SEP-2012

BK140091-0  IT Synergistics, LLC  
115 Tree Street  
Flowood, MS 39232  
Trade Name: DVac Elite v 2.0  
Cleared Date: 09-APR-2014

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
Trade Name: LIFECODES HLA-DPA1/B1 SSO Typing Kit
Cleared Date: 11-MAY-2016

BK150343-0 Immucor Transplant Diagnostics, Inc.
550 West Avenue
Stamford, CT 06902-6352
Trade Name: LIFECODES MATCH IT! DNA Software v1.2
Cleared Date: 11-MAY-2016

BK820019-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Checkcell
Cleared Date: 15-DEC-1982

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

BK830005-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: 30% Bovine Albumin
Cleared Date: 17-MAR-1983

BK830007-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Low Ionic Strength Solution (LISS)
Cleared Date: 11-MAY-1983

BK830013-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Rh-Hr Control
Cleared Date: 19-JUL-1983

BK830021-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Anti-N Lectin
Cleared Date: 07-NOV-1983

BK830022-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ImmuAdd
Cleared Date: 07-NOV-1983

BK830018-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30091-5625
Trade Name: ABS2000
Cleared Date: 30-JUN-1998

BK960020-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R Control Cells
Cleared Date: 04-JUN-1997

BK000021-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-S Solid Phase Assay
Cleared Date: 22-JUN-2000

BK000024-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ABS2000, Version 2 software
(2.05.00A and 2.05.00B)
Cleared Date: 03-JUL-2001

BK010002-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ABS2000 (version 1.00.30A SR-1)
Cleared Date: 16-FEB-2001

BK010020-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ABS2000 with Version 2.05.00A Software
ABS2000 with Version 2.05.00B Software
ABS2000 with Version 1.00.30A SR-2 Software
Cleared Date: 24-SEP-2001

BK020053-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R Ready Indicator Red Cells
Cleared Date: 27-JAN-2003

BK020054-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R Control Cells
Cleared Date: 27-JAN-2003

BK040010-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Monoclonal Control
Cleared Date: 23-APR-2004

BK040013-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Galileo version 1.3.6 SP4
Cleared Date: 23-APR-2004

BK040014-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Galileo QC Cell
Cleared Date: 22-APR-2004

BK040023-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: DAT Positive Control Cell
Cleared Date: 23-APR-2004

BK040024-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R Select Solid Phase System
Cleared Date: 28-APR-2004

BK040057-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Check cell (Weak)
Cleared Date: 06-OCT-2004

BK050050-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-CMV Galileo Automated Blood Bank System
Cleared Date: 14-NOV-2005

BK060009-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Galileo Automated Blood Bank System with Capture-S Syphilis Screening Assay
Cleared Date: 11-APR-2006

BK060016-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: corQC Test System
Cleared Date: 09-MAY-2006

BK070013-0 Immucor, Inc.
3130 Gateway Drive
Trade Name: Monoclonal Control
Cleared Date: 14-JUN-2007

Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625

Trade Name: DAT Positive Control Cell
Cleared Date: 14-JUN-2007

Trade Name: WB corQC
Cleared Date: 14-JUN-2007

Trade Name: Galileo Echo Automated Blood Bank System
Cleared Date: 14-JUN-2007

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 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 - 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

BK110054-0  Immunetics, Inc.  
27 Drydock Avenue  
Boston, MA 02210-2377  
Trade Name: BacTx(R) Bacterial Detection Kit for Platelets  
Cleared Date: 11-JUN-2012

BK130017-0  Immunetics, Inc.  
27 Drydock Avenue  
Boston, MA 02210-2377  
Trade Name: BacTx Reader BacTx Software BacTx® Bacterial Detection Kit for Detection of Bacteria in Platelets  
Cleared Date: 12-AUG-2013

BK170149-0  Immunetics, Inc.  
27 Drydock Avenue  
Boston, MA 02210-2377  
Trade Name: BacTx Bacterial Detection Kits  
Cleared Date: 16-APR-2018

BK910033-0  In-Touch Company  
101 N 700 West  
Salt Lake City, UT 84954  
Trade Name: Alton Dean Model 537 Blood Warmer  
Cleared Date: 18-NOV-1992

BK960068-0  Indico, Inc.  
Suite 137  
6325 103 Street
Edmonton, ALBERTA Canada T6H 5H6
Trade Name: RadTag
Cleared Date: 30-OCT-1996

BK000008-0 Indico, Inc.
Suite 137
6325 103 Street
Edmonton, ALBERTA Canada T6H 5H6
Trade Name: RadTag
Cleared Date: 01-MAR-2000

BK950064-0 Informatics
4000 Kruso Way Place
Building 3 Suite 210
Lake Oswego, OR 97035
Trade Name: Lifeline Blood Bank Data Management System, Release 4.2
Cleared Date: 01-JUL-1998

BK950032-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: Abbott Data Management System, version 3.0.2
Cleared Date: 18-AUG-1998
Cleared Under Abbott Laboratories

BK950037-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: Components & Distribution Information System (CDIS)
Cleared Date: 26-AUG-1996

BK950045-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: DONOR MANAGEMENT INFORMATION SYSTEMS
Cleared Date: 26-AUG-1996

BK980020-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: Plasma Center Management System - Version 1.0
Cleared Date: 31-JUL-1998

BK980028-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: PCMS - version 1.1
Cleared Date: 04-SEP-1998

BK990016-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: Surround System - 1.0
Cleared Date: 27-AUG-1999

BK990029-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: Plasma Center Management System (PCMS) Version 1.2
Cleared Date: 13-OCT-1999

BK000016-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: Information Data Management
Surround System - 2.0
Cleared Date: 07-APR-2000

BK990046-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: Plasma Center Management System
(PCMS) - Version 2.0
Cleared Date: 06-JAN-2000

BK010028-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: IDM Surround System - 3.0
Cleared Date: 05-SEP-2001

BK020038-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: Surround System, Version 3.2
Cleared Date: 08-OCT-2002

BK050014-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: IDM Prelude System, Version 1.1
Cleared Date: 18-JUL-2005

BK070031-0 Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
Trade Name: IDM Symphony System - 2.0
Cleared Date: 13-DEC-2007

BK860042-0 Insta Cool, Inc of North America
11300 Sanders Drive, Suite 14
Rancho Cordova, CA 95742
Trade Name: Insta Cool Model BP2502
Cleared Date: 04-MAR-1987

BK900032-0 Insta Cool, Inc of North America
11300 Sanders Drive, Suite 14
Rancho Cordova, CA 95742
Trade Name: MP III
Cleared Date: 30-MAR-1992

BK910011-0 Insta Cool, Inc of North America
11300 Sanders Drive, Suite 14
Rancho Cordova, CA 95742
Trade Name: MT-200 FROZEN PLASMA THAWER
Cleared Date: 19-DEC-1991

BK940019-0 Insta Cool, Inc of North America
11300 Sanders Drive, Suite 14
Rancho Cordova, CA 95742
Trade Name: Hemopharm PB-500 Pocket Sealer
Cleared Date: 26-SEP-1994

BK850016-0 Integrated Diagnostics, Inc.
1901 Sulphur Spring Road
Baltimore, MD 1227
Trade Name: HLA COMPREHENSIVE TRAY
Cleared Date: 30-DEC-1985

BK870018-0 Integrated Diagnostics, Inc.
1901 Sulphur Spring Road
Baltimore, MD 1227
Trade Name: INDX HLA-DR, DQ Lymphocyte Phenotyping Tray
Cleared Date: 28-OCT-1987

BK080006-0 IntelliDOT Corporation
13520 Evening Creek Drive North, Suite 400
San Diego, CA 92128
Trade Name: IntelliDOT Blood Product Administration
Cleared Date: 13-JUN-2008

BK820001-0 International Business Machines
Princeton, NJ 08540
Trade Name: IBM 2991
Cleared Date: 28-JUN-1982

BK830003-0 International Business Machines
Princeton, NJ 08540
Trade Name: IBM 2991 - Single Unit Leukocytes from Whole Blood
Cleared Date: 27-MAY-1983

BK830020-0 International Business Machines
Princeton, NJ 08540
Trade Name: Plastic for 2997
Plastic for 2991
Cleared Date: 27-OCT-1983

BK830024-0 International Business Machines
Princeton, NJ 08540
Trade Name: Plastic for 2991
Plastic for 2997
Cleared Date: 09-MAR-1984

BK820020-0 International Equipment Company
300 Second Avenue
Needham Heights, MA 02194
Trade Name: IEC Centra-W Cell Washer
Cleared Date: 05-APR-1983

BK940004-0 International Equipment Company
300 Second Avenue
Needham Heights, MA 02194
Trade Name: Seromax
Cleared Date: 08-APR-1994

BK910018-0 International Specialty Products
1361 Alps Road
Wayne, NJ 07470
Trade Name: RAD-SURE BLOOD IRRADIATION LABEL
Cleared Date: 12-MAR-1992
<table>
<thead>
<tr>
<th>Company</th>
<th>Address</th>
<th>Trade Name</th>
<th>Cleared Date</th>
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<tbody>
<tr>
<td>International Specialty</td>
<td>1361 Alps Rd., Wayne, NJ 07470</td>
<td>RAD-Sure 2500</td>
<td>01-APR-1993</td>
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<td>Products</td>
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<td>Intra-Lock International</td>
<td>6560 West Rogers Circle, Boca Raton, FL 33487</td>
<td>Intra-Spin System</td>
<td>28-JAN-2013</td>
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<tr>
<td>Jewett Refrigerator Co., Inc.</td>
<td>2-18 Letchworth Street, Buffalo, NY 14213-1098</td>
<td>Jewett Models BPL13, BPL21, BPL25</td>
<td>08-AUG-1996</td>
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<td>Models BBR17, BBR25, BBR37 &amp; BBR55</td>
<td>30-OCT-1996</td>
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<td>Jewett Model CT1</td>
<td>06-FEB-1997</td>
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<td>Jewett Model CTF-1</td>
<td>16-APR-1997</td>
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<td>Jewett Model BBWM3</td>
<td>18-JUL-1997</td>
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<td>Jewett Model BPL55</td>
<td>15-OCT-1997</td>
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<td>Jouan, Inc.</td>
<td>Route 8, Box 1202; P.O. Box 2716, Winchester, VA 22601</td>
<td>Model LR5.22 centrifuge</td>
<td>15-DEC-1986</td>
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<tr>
<td>Jouan, Inc.</td>
<td>Route 8, Box 1202; P.O. Box 2716, Winchester, VA 22601</td>
<td>Model GR 4.11 centrifuge</td>
<td>20-FEB-1987</td>
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<tr>
<td>Jouan, Inc.</td>
<td>Route 8, Box 1202; P.O. Box 2716, Winchester, VA 22601</td>
<td>Model KR4-22 Centrifuge</td>
<td>02-FEB-1990</td>
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BK000003-0  Kawasumi Laboratories, Inc.
1900 K Street
Washington, DC 20006
Trade Name: Kawasumi Laboratories Phlebotomy System
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

BK160004-0 LifeSouth Community Blood Centers Inc.
4039 Newberry Road
Gainesville, FL 32607
Trade Name: Integrated Blood Bank Information System (IBBIS), Version 4.0
Cleared Date: 29-MAR-2016

BK830006-0 Liquid Crystal Products, Inc.
724 Algonquin Road
Arlington Heights, IL 60005
Trade Name: HemoTemp II Blood Temperature Indicator
Cleared Date: 04-MAY-1983

BK990013-0 Ljungberg & Kogel
C/O Kamm & Associates
333 Milford Rd.
Deerfield, IL 60015
Trade Name: Biomixer 330 & Biomixer 323
Cleared Date: 07-JUL-1999

BK090010-0 Ljungberg & Kogel
C/O Kamm & Associates
333 Milford Rd.
Deerfield, IL 60015
Trade Name: Biomixer BM330 with XBee (Wireless) Option
Cleared Date: 17-JUL-2009

BK180232-0 MAK-SYSTEM SA International Group
10 Avenue de la Grande-Armee
Paris France 75017
Trade Name: Patient Health Software (P.H.S) - 2.0
Cleared Date: 18-OCT-2018

BK960050-0 MAK-System
Z.I. Paris Nord II
14, Rue de la Perdrix
95946 Roissy C.D.G. CEDEX, France B.P. 50035
Trade Name: Progesa
Cleared Date: 10-DEC-1998

BK060035-0 MAK-System
10 Avenue de la Grande Armee
75017 Paris, France 75017
Trade Name: Patient Health Software - 1.0
Cleared Date: 09-MAY-2007

BK070062-0 MAK-System
10 Avenue de la Grande Armee
75017 Paris, France 75017
Trade Name: PROGESA - 4.4h
Cleared Date: 26-OCT-2007

BK080002-0 MAK-System
10 Avenue de la Grande Armee
75017 Paris, France 75017
Trade Name: ePROGESA - 5.0.1
Cleared Date: 13-MAY-2008

BK960029-0 MEDITECH Medical Information Technology, Inc.
MEDITECH Circle
Westwood, MA 02090
Trade Name: MEDITECH
Cleared Date: 19-MAR-1999

BK980046-0 MEDITECH Medical Information Technology, Inc.
MEDITECH Circle
Westwood, MA 02090
Trade Name: Magic Client Server - 5.1
Cleared Date: 08-FEB-2000

BK060029-0 MEDITECH Medical Information Technology, Inc.
MEDITECH Circle
Westwood, MA 02090
Trade Name: MEDITECH MAGIC Blood Bank Software - 4.9
Cleared Date: 06-FEB-2007

BK080037-0 MEDITECH Medical Information Technology, Inc.
MEDITECH Circle
Westwood, MA 02090
Trade Name: MEDITECH Client Server Blood bank module 5.6 - v5.6
Cleared Date: 30-OCT-2008

BK080061-0 MEDIWARE INFORMATION SYSTEMS, INC.
11711 West 79th Street
Lenexa, KS 66214
Trade Name: HCLL Donor
Cleared Date: 02-DEC-2008

BK100043-0 MEDIWARE INFORMATION SYSTEMS, INC.
11711 West 79th Street
BK100057-0  MEDIWARE INFORMATION SYSTEMS, INC.
11711 West 79th Street
Lenexa, KS 66214
Trade Name: LifeTrak/Donor - 4.6.0
Cleared Date: 21-OCT-2010

BK100069-0  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

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 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
Leucolab LCG2 Leukoreduction Systems for AS-1 and AS-3 Red Blood Cells
Leucolab LCG2 Leukoreduction Systems for AS-1, AS-3 and AS-5 Red Blood Cells
Cleared Date: 22-FEB-2013
BK160095-0  MacoProductions S.A.S.
200 chaussée 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 chaussée 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 chaussée Fernand Forest
Tourcoing France 59200
Trade Name: MacoPress Smart Smarter and DMS Plus
Cleared Date: 24-JAN-2019
BK960075-0  Mallinckrodt Medical, Inc.
Trade Name: Alton Dean Fluid Warmer, FW-537  
Cleared Date: 28-FEB-1997

Trade Name: Horizon MobileCare Transfusion  
Cleared Date: 28-MAY-2010

Trade Name: MEDITECH Expanse Blood Bank  
Cleared Date: 12-SEP-2018

Trade Name: sHLA-STAT B27 ELISA for HLA-B27 Typing  
Cleared Date: 20-AUG-1993

Trade Name: DG Gel Extended Control  
Cleared Date: 11-APR-2014

Trade Name: DG Gel Essential Control  
Cleared Date: 17-JAN-2019

Trade Name: Hemocare Blood Bank Management System - Revision 5.2  
Cleared Date: 10-DEC-1998

Trade Name: LifeTrak Lab - 2.03  
Cleared Date: 17-JUN-2002

Trade Name: Hemocare LifeLine - Version, 1.0  
Cleared Date: 14-FEB-2003

Trade Name: HCLL - 2.6  
Cleared Date: 08-APR-2004

Trade Name: Instrument Interface Engine - 1.0
Cleared Date: 16-JUL-2004

BK050011-0 Medware Information Systems, Inc.
4545 Fuller Drive, Ste 320
Irving, TX 75038
Trade Name: HCLL Donor - 1.0
Cleared Date: 10-MAY-2005

BK060019-0 Medware Information Systems, Inc.
4545 Fuller Drive, Ste 320
Irving, TX 75038
Trade Name: Life Trak / Donor - 3.01
Cleared Date: 21-JUN-2006

BK080049-0 Medware 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 Medware 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 Medware Information Systems, Inc.
1900 Spring Road, Suite 450
Oak Brook Service Center
Oak Brook, IL 60523
Trade Name: LifeTrak(R) 2012
Cleared Date: 05-SEP-2012

BK160066-0 Medware Information Systems, Inc.
11711 West 79th St
Lenexa, KS 66214
Trade Name: HCLL(TM) Transfusion 2015 R2
Cleared Date: 30-SEP-2016

BK180200-0 Medware 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 BPF48 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
Trade Name: Pall Autoprocessor™ System
Cleared Date: 07-SEP-1994
Cleared Under Pall Bio Medical

Trade Name: The Pall Celeris fPC System
Cleared Date: 24-FEB-2011

Trade Name: Plasmapheresis Data System III - 1.0
Cleared Date: 05-FEB-2002

Trade Name: Magellan Autologous Platelet
Separation System
Cleared Date: 03-SEP-2003

Trade Name: Magellan Autologous Platelet
Separator System
Cleared Date: 09-NOV-2004

Trade Name: CAPTIA TM Syphilis-G
Cleared Date: 03-JAN-1995

Trade Name: MGR Model ERB-5-0378
Cleared Date: 12-MAR-1992

Trade Name: MTS Diluent 2
Cleared Date: 29-SEP-1993

Trade Name: MTS Centrifuge
Cleared Date: 29-SEP-1993

Trade Name: MTS Buffered Gel Card
Cleared Date: 29-SEP-1993
BK930030-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Diluent 1
Cleared Date: 29-SEP-1993

BK940034-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Diluent 2 Plus
Cleared Date: 12-JAN-1994

BK950025-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Control Card
Cleared Date: 27-JUL-1994

BK950026-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Incubator
Cleared Date: 08-MAY-1995

BK950027-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Work Table
Cleared Date: 15-MAY-1995

BK950028-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Dispenser (0.5ml and 1.0ml)
Cleared Date: 27-JUN-1995

BK960013-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS-Centrifuge Model NU 9310
Cleared Date: 15-APR-1996

BK980016-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: ID-Tipmaster
Cleared Date: 29-OCT-1998

BK990012-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Reader M
Cleared Date: 19-NOV-1999

BK000018-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Reader SA
Cleared Date: 21-NOV-2000

BK010021-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Incubator II
Cleared Date: 01-OCT-2001

BK030023-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: Ortho ProVue, Software Version: 2.10
Cleared Date: 14-MAY-2003

BK090013-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: ORTHO ProVue, version 3.1
Cleared Date: 04-JUN-2009

BK110029-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: Ortho ProVue Analyzer Version 3.1
Patch 1 (V3.1.1)
Cleared Date: 14-JUL-2011

BK150280-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Buffered Gel Card
MTS Monoclonal Control Card
Cleared Date: 14-AUG-2015

BK160061-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS TM Buffered Gel Card
MTS TM Monoclonal Control Card
Cleared Date: 21-OCT-2016

BK190339-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS™ Buffered Gel Card
Cleared Date: 08-JUL-2019

BK190400-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Buffered Gel Card
Cleared Date: 17-DEC-2019

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-K-1 Bld. and Plasma Warmer
Cleared Date: 29-JUL-1993

BK940003-0  Microwave Medical System
310-312 School St.
Acton, MA 01720
Trade Name: 500 Qwik I TM
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 - 2.0
Cleared Date: 22-DEC-2003

BK040065-0  Misys Healthcare Systems
4801 East Broadway Boulevard
Tucson, AZ 85711
Trade Name: Misys Laboratory Blood Bank and
Blood Donor - 6.0.1
Cleared Date: 22-OCT-2004

BK940044-0  Mona Barres
516 Sean Dr.
Metairie, 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: Compocool
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
Clear Date: 05-DEC-2012

BK180283-0 Nanoentek, Inc.
12f, 5. Digital-Ro 26-Gil Guro-Gu
Seoul Korea, Republic Of 152-740
Trade Name: ADAMII CD34 System
Clear Date: 09-AUG-2019

BK950042-0 National Hospital Specialties
104 Johnson Avenue
Hackensack, NJ 07601
Trade Name: Genesis Blood Collection Mixer
Clear Date: 19-SEP-1995

BK840016-0 Neocyte
199 Weymouth Street
Rockland, MA 02370
Trade Name: NEOPACK System
Clear 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
Clear 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
Clear 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
Clear Date: 12-OCT-2006

BK180301-0 Newmarket Biomedical Ltd
Unit 1 Lanwades Business Park
Kentford United Kingdom CB8 7PN
Trade Name: PK7400 TP HA Controls
PK7400 TP HA Reagent
Clear Date: 01-AUG-2019

BK920020-0 Nor-Lake, Inc.
Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name: NSBR211, NSBR482, and NSB763 Blood Refrigerators
Clear 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)
Clear 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)
Clear Date: 13-APR-1995


BK930004-0 Nor-Lake, Inc.  
Second and Elm Str. P.O. Box 248  
Hudson, WI 54016  
Trade Name: NSBF211 (Nor-Lake Scientific Freezers, 21ft Single Door)  
Cleared Date: 13-APR-1995

BK930005-0 Nor-Lake, Inc.  
Second and Elm Str. P.O. Box 248  
Hudson, WI 54016  
Trade Name: NSBF482 (Nor-Lake Scientific Plasma Freezers, 48ft Double Door)  
Cleared Date: 13-APR-1995

BK930006-0 Nor-Lake, Inc.  
Second and Elm Str. P.O. Box 248  
Hudson, WI 54016  
Trade Name: NSBF61 (Nor-Lake Scientific Plasma Freezer, 6ft Single Door)  
Cleared Date: 13-APR-1995

BK900023-0 North American Biologicals, Inc.  
16500 N.W. 15th Avenue  
Miami, FL 33169  
Trade Name: QC-HIV  
Cleared Date: 13-NOV-1991

BK910006-0 North American Biologicals, Inc.  
16500 N.W. 15th Avenue  
Miami, FL 33169  
Trade Name: QC-Hepatitis  
Cleared Date: 12-MAR-1992

BK920015-0 North American Biologicals, Inc.  
16500 N.W. 15th Avenue  
Miami, FL 33169  
Trade Name: VirocheQC 1  
Cleared Date: 20-MAY-1993

BK910028-0 North American Technical Services Corp.  
407 E Main St.  
Port Jefferson, NY 11777  
Trade Name: ASTOTHERM/ASTOTUBE  
Cleared Date: 13-JUL-1992

BK110060-0 Novartis Vaccines and Diagnostics, Inc.  
4560 Horton St.  
Emeryville, CA 94608-2916  
Trade Name: PROCLEIX® NAT TRACKER® Version 3.0 Software  
Cleared Date: 01-DEC-2011

BK930023-0 Nu-Quest, Inc.  
1031 Meadowview Drive  
Webb City, MO 64870  
Trade Name: Little Pig Sticker  
Cleared Date: 24-FEB-1994

BK830017-0 Nuclear-Medical Laboratories, Division  
1800 Hurd Drive  
Irving, TX 75061  
Trade Name: Hepa-SHure  
Cleared Date: 07-OCT-1983
BK080022-0  Olerup SSP AB
Hasselstigen 1
SE 133 33 Saltsjobaden
, Sweden
Trade Name: Olerup SSP HLA Typing Kits
Cleared Date: 20-FEB-2009

BK090042-0  Olerup SSP AB
Hasselstigen 1
SE 133 33 Saltsjobaden
, Sweden
Trade Name: Olerup SSP HLA Typing Kits
Cleared Date: 11-SEP-2009

BK010040-0  Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: Olympus PK 7200 Automated Microplate System
Cleared Date: 25-OCT-2001

BK020024-0  Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: Olympus PK7200 Automated Microplate System
Cleared Date: 08-JUL-2002

BK030009-0  Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: Olympus PK7200 Automated Microplate System
Cleared Date: 03-MAR-2003

BK040003-0  Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: Olympus PK7200 Automated Microplate System
Cleared Date: 06-FEB-2004

BK040070-0  Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: Tango Automated Blood Bank Analyzer System
Cleared Date: 22-MAR-2005

BK050076-0  Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: TANGO Automated Blood Bank Analyzer System (HW Version 02/SW Version 3.0)
Cleared Date: 16-DEC-2005

BK060024-0  Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: Olympus Bromelin Olympus PK7300 Automated Microplate System Olympus System Control
Cleared Date: 14-MAY-2007
BK060034-0  Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: TANGO Automated Blood Bank Analyzer System
Cleared Date: 28-AUG-2006

BK090036-0  Olympus America Inc., Diagnostic Systems Division
3500 Corporate Parkway
Center Valley, PA 18034
Trade Name: Olympus PK7300 Automated Microplate System
Cleared Date: 13-JAN-2010

BK860004-0  Olympus Corporation
4 Nevada Drive
Lake Success, NY 11042
Trade Name: Olympus PK7100
Cleared Date: 14-MAY-1986

BK870025-0  Olympus Corporation
4 Nevada Drive
Lake Success, NY 11042
Trade Name: Olympus PK7100 Automated Blood Grouping System
Cleared Date: 09-OCT-1987

BK890030-0  Olympus Corporation
4 Nevada Drive
Lake Success, NY 11042
Trade Name: SynthEIA Software System
Cleared Date: 23-JAN-1991

BK930024-0  Olympus Corporation
4 Nevada Drive
Lake Success, NY 11042
Trade Name: Olympus PK7200 Blood Grouping Analyzer
Cleared Date: 26-JAN-1994

BK140093-0  Omrix Biopharmaceuticals Ltd.
PO Box 151, 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 LABScan(TM) 3D
Cleared Date: 20-DEC-2012

BK130009-0  One Lambda, Inc
21001 Kittridge St
Canoga Park, CA 91303
Trade Name: LABScreen® for use with LABScan(TM) 3D
Cleared Date: 06-NOV-2013

BK140141-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LABScreen(R) Multi
Cleared Date: 25-NOV-2014

BK910021-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: Lifesource Flash Bag
Cleared Date: 08-JUN-1992

BK920007-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: Lambda Monoclonal Tray Class I and II
Cleared Date: 28-DEC-1992

BK920009-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: Anti-B27 FITC Conjugated Monoclonal Antibody
Cleared Date: 28-MAR-1997

BK960011-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: Lambda Antigen Tray
Cleared Date: 03-JUL-1997

BK960053-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: Anti-B27 FITC/CD3PE Conjugated Monoclonal Antibody
Cleared Date: 30-OCT-1996

BK960062-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: Micro SSP HLA Class II DNA Typing Kit
Cleared Date: 11-FEB-1998

BK980015-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: FlowPRA
Cleared Date: 23-JUL-1999

BK020055-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LABTYPE SSO Typing Test
Cleared Date: 04-FEB-2003

BK030069-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LABScreen Products for use with LABScan 100 flow analyzer
Cleared Date: 31-DEC-2003

BK040049-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LabType Visual
Cleared Date: 09-AUG-2004

BK050008-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LABScreen Software
Cleared Date: 08-JUL-2005

BK050070-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: HLA Visual Software version 1.0
Cleared Date: 30-JAN-2006

BK050071-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: HLA Tools Software version 1.0
Cleared Date: 30-JAN-2006

BK070070-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: HLA Fusion Software v 1.0
Cleared Date: 10-MAR-2008

BK080071-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LABScreen Multi
Cleared Date: 10-APR-2009

BK100068-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: HNA Genotyping Trays
Cleared Date: 25-AUG-2011

BK160017-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: HLA Fusion
Cleared Date: 08-MAR-2017

BK160018-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LABTypeTM XR and CWD DNA Typing Test
Cleared Date: 06-MAR-2017

BK170053-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LABType? CWD Class I C Locus Typing Test
LABType? CWD Class I C Locus Typing Test - 20 tests
LABType? XR Class I C Locus Typing
Test
LABType? XR Class I C Locus Typing
Test - 20 tests
Cleared Date: 05-OCT-2017

BK190322-0  Or Sense Ltd
17 Ha’Mefalsim St
Petah Tikva, Kiryat Arie Israel 4951447
Trade Name: NBM-200 Pulse Oximeter and Hemoglobin Monitor
Cleared Date: 09-MAY-2019

BK030036-0  OriGen BioMedical
7000 Burleson Road, Bldg. D
Austin, TX 78744
Trade Name: OriGen Cryostore Freezing Bags
Cleared Date: 01-OCT-2003

BK140116-0  OriGen BioMedical
7000 Burleson Road, Building D
Austin, TX 78744
Trade Name: OriGen Transfer Bag
Cleared Date: 19-OCT-2016

BK180278-0  OriGen BioMedical
7000 Burleson Road, Building D
Austin, TX 78744
Trade Name: OriGen Cryostore Multi-Chamber Freezing Bags
Cleared Date: 21-NOV-2018

BK820003-0  Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO Confidence System
Cleared Date: 10-AUG-1982

BK820006-0  Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: Simwash
Cleared Date: 13-APR-1983

BK830023-0  Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: TYTEM Typing and Detection System
Cleared Date: 08-DEC-1983

BK840017-0  Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO Cell Suspension Tube
Cleared Date: 16-NOV-1984

BK890021-0  Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: Ortho Confidence System
Cleared Date: 23-OCT-1989

BK920034-0  Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: Ortho BioVue System
Cleared Date: 09-MAY-1995  
BK960003-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: Ortho Summit System  
Cleared Date: 19-OCT-1998

Cleared Date: 19-OCT-1998  
BK960052-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: Ortho Summit Processor  
Cleared Date: 19-OCT-1998

Cleared Date: 03-APR-2000  
BK990030-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: Ortho Lab with Ortho Lab IC (Instrument Concentrator)  
Cleared Date: 03-APR-2000

Cleared Date: 03-NOV-2006  
BK050044-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: Genetic Systems HIV-1/HIV-2 PLUS O Ortho Assay Protocol Disk  
Cleared Date: 03-NOV-2006

Cleared Date: 13-JAN-2006  
BK050046-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: Genetic Systems HBsAg ELA 3.0 Ortho Assay Protocol Disk  
Cleared Date: 13-JAN-2006

Cleared Date: 10-APR-2008  
BK070028-0 Ortho-Clinical Diagnostics, Inc.  
100 Indigo Creek Drive  
Rochester, NY 14626-5101  
Trade Name: VITROS Immunodiagnostic Products Anti-HIV 1+2 Controls  
Cleared Date: 10-APR-2008

Cleared Date: 27-MAY-2009  
BK090074-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: Ortho Summit System  
Cleared Date: 27-MAY-2009

Cleared Date: 22-JUL-2010  
BK100040-0 Ortho-Clinical Diagnostics, Inc.  
100 Indigo Creek Drive  
Rochester, NY 14626-5101  
Trade Name: VITROS Immunodiagnostic Products Anti-HIV 1+2 Controls  
Cleared Date: 22-JUL-2010

Cleared Date: 28-OCT-2010  
BK100061-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VERSELa₂ Pipetter as part of the ORTHO Summit System  
Cleared Date: 28-OCT-2010

Cleared Date: 28-OCT-2010  
BK110026-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606
Trade Name: Ortho Summit System (OSS)  
Cleared Date: 28-JUN-2011

BK120006-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VERSEIA Pipetter as Part of the ORTHO Summit System (OSS) v3.0  
Cleared Date: 15-MAR-2012

BK130006-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VERSEIA® Integrated Processor (VIP)  
Cleared Date: 23-MAY-2013

BK130032-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO (TM) Workstation  
Cleared Date: 09-AUG-2013

BK140207-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VISION Analyzer  
Cleared Date: 14-AUG-2015

BK160058-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VISION Max Analyzer  
Cleared Date: 21-OCT-2016

BK190338-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VISION® Analyzer  
Cleared Date: 09-JUL-2019

BK190399-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VISION Max Analyzer  
Cleared Date: 17-DEC-2019

BK040017-0 Orthogen Therapeutics, GmbH  
Gräf-Adolf-Str. 43  
D-40210 Düsseldorf, Germany  
Trade Name: Osteokin System  
Cleared Date: 23-JUN-2004

BK080014-0 Pall Corporation  
25 Harbor Park Drive  
Port Washington, NY 11050-4630  
Trade Name: Pall eBDS  
Cleared Date: 13-FEB-2009  
Cleared Under Pall Life Sciences

BK150314-0 Pall Corporation  
25 Harbor Park Drive  
Port Washington, NY 11050-4630  
Trade Name: Pall® Briostor® Transfer/Freezing
Bag Set

Cleared Date: 16-JUN-2016

BK120029-0 PatientSafe Solutions
5375 Mira Sorrento Place
Suite 500
San Diego, CA 92121
Trade Name: Patient Touch(TM) Blood Product Administration System v3.2.1
Cleared Date: 13-NOV-2012

BK820002-0 Pel-Freez Clinical Systems, LLC
PO Box 68
Rogers, AR 72756
Trade Name: Not available from BLT migrated data.
Cleared Date: 06-OCT-1982

BK820023-0 Pel-Freez Clinical Systems, LLC
PO Box 68
Rogers, AR 72756
Trade Name: Leukocyte Typing Serum (Human) (Tray Package)
Cleared Date: 12-JAN-1983

BK850004-0 Pel-Freez Clinical Systems, LLC
9099 N. Deerbrook Trail
Brown Deer, WI 53223
Trade Name: Frozen Leukocyte Panel (Human)
Cleared Date: 01-AUG-1985

BK000019-0 Pel-Freez Clinical Systems, LLC
9099 N. Deerbrook Trail
Brown Deer, WI 53223
Trade Name: UniTray SSP HLA Typing Kits
Cleared Date: 29-JAN-2001

BK020068-0 Pel-Freez Clinical Systems, LLC
9099 N. Deerbrook Trail
Brown Deer, WI 53223
Trade Name: Pel Freez HLA High Resolution SSP UniTray
Cleared Date: 14-JAN-2003

BK030003-0 Pel-Freez Clinical Systems, LLC
9099 N. Deerbrook Trail
Brown Deer, WI 53223
Trade Name: UniMatch Plus
Cleared Date: 25-FEB-2003

BK050055-0 Perfusion Partners & Associates, Inc.
6227 Foxfire Lane
Fort Myers, FL 33912
Trade Name: GenesisCS Component Concentrating System
Cleared Date: 13-OCT-2006

BK900018-0 Polar Products, Inc.
2808 Oregon Ct. Bldg K-4
Torrance, CA 90503
Trade Name: Polar Products' Model MTE-58L
Cleared Date: 30-AUG-1990

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.
Ibaizabal bidea, Edificio 504
Parque Tecnológico 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

BK000036-0 R & D Systems, Inc
614 McKinley Place N.E.
Minneapolis, MN 55413
Trade Name: R & D Leuko-Reduced Plt Control
Cleared Date: 13-DEC-2000

BK040012-0 R & D Systems, Inc
614 McKinley Place N.E.
Minneapolis, MN 55413
Trade Name: R&D Donor Checker Hematology Control
Cleared Date: 05-MAR-2004
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

RedDress Ltd
Shkedim Street 11
Pardes Hanna, Israel 370110
Trade Name: RD2 System
Cleared Date: 08-NOV-2019

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

RegenLab SA
3428 Avenue Marcil
Montreal, Quebec Canada H4A 2Z3
Trade Name: A-CP-Kit Family Kits
Cleared Date: 08-AUG-2013

RegenLab SA
P. O. Box 9002
Pleasanton, CA 94588-0900
Trade Name: COBAS AmpliScreen Data Output Management System (DOMS) - 1.00.04
Cleared Date: 10-DEC-2002

BK140195-0 Roche Molecular Systems, Inc.
4300 Hacienda Drive
P.O. Box 9002
Pleasanton, CA 94588-0900
Trade Name: Cobas p 680 Instrument
Cleared Date: 20-OCT-2016

BK140196-0 Roche Molecular Systems, Inc.
4300 Hacienda Drive
P.O. Box 9002
Pleasanton, CA 94588-0900
Trade Name: cobas p 680 Instrument
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  
Gainseville, FL 32608
Trade Name: The Saber (Segment Piercing Device)  
Cleared Date: 13-NOV-1995

BK090047-0  
SPINESMITH PARTNERS LP  
93 Red River  
Austin, TX 78701
Trade Name: Fusionary Graft Delivery System  
Cleared Date: 10-FEB-2010

BK050052-0  
STEMCO Biomedical, Inc.  
2810 Meridan Parkway  
Suite 148  
Durham, NC 27713  
Trade Name: Aldecoumt 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.
BK870028-0  Saturn BioTech Corporation
P.O. Box 3823
Littleton, CO 80161
Trade Name: RMED Finger Heme Trap
Cleared Date: 01-FEB-1988

BK940029-0  Scimed Life Systems, Inc.
6655 Wedgewood Rd.
Maple Grove, MN 55311
Trade Name: Scimed UltraFuse Coron.
Infusion/Guidewire Exchange Catheter
Cleared Date: 15-MAR-1995

BK870011-0  Seabrook Medical Systems, Inc.
673 Wilmer 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.
3535 Firewheel Drive
Suite A
Flower Mound, TX 75028-2628
Trade Name: Hot Shot Fluid Warmer Model 100
Hot Shot Fluid Warmer Model 101
Hot Shot Fluid Warmer Model 102
Hot Shot Fluid Warmer Model 103
Cleared Date: 13-OCT-1999

BK090077-0  Siemens Healthcare Diagnostics, Inc.
P.O. Box 2466
Berkeley, CA 94702
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 28-DEC-2009
Cleared Under Siemens Healthcare Diagnostics Inc.

BK110007-0 Siemens Healthcare Diagnostics, Inc.
P.O. Box 2466
Berkeley, CA 94702
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 04-MAR-2011
Cleared Under Siemens Healthcare Diagnostics Inc.

BK120013-0 Siemens Healthcare Diagnostics, Inc.
P.O. Box 2466
Berkeley, CA 94702
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 27-MAR-2012
Cleared Under Siemens Healthcare Diagnostics Inc.

BK140152-0 Siemens Healthcare Diagnostics, Inc.
511 Benedict Ave
Tarrytown, NY 10591
Trade Name: ADVIA Centaur System (Software Version 4.0 with SP4)
Cleared Date: 08-JUN-2015

BK140153-0 Siemens Healthcare Diagnostics, Inc.
511 Benedict Ave
Tarrytown, NY 10591
Trade Name: ADVIA Centaur XP System (SW v 7.1)
Cleared Date: 08-JUN-2015

BK960051-0 Siemens Medical Solutions Diagnostics
800 Dwight Way
Berkeley, CA 94701-1986
Trade Name: PPIS - Version 2.0
Cleared Date: 07-AUG-1998
Cleared Under Bayer Corporation

BK990024-0 Siemens Medical Solutions Diagnostics
800 Dwight Way
Berkeley, CA 94701-1986
Trade Name: Plasma Procurement Information System (PPIS) - 3.0
Cleared Date: 03-NOV-1999
Cleared Under Bayer Corporation

BK990037-0 Siemens Medical Solutions Diagnostics
800 Dwight Way
Berkeley, CA 94701-1986
Trade Name: Plasma Procurement Information System (PPIS) - Version 4.0
Cleared Date: 17-NOV-1999
Cleared Under Bayer Corporation

BK060015-0 Siemens Medical Solutions Diagnostics
P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 21-MAR-2006
Cleared Under Bayer Healthcare Diagnostics Division
BK030018-0  Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name: SoftBank II - 22
Cleared Date: 11-SEP-2002

BK040028-0  Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name: SoftBank II - 23
Cleared Date: 17-APR-2003

BK040048-0  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

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, Preserved
Cleared Date: 02-NOV-1987

BK870016-0  Stephens Scientific
7 Astro Place Box 1116
Denville, NJ 07834
Trade Name: Certified Saline, Preserved
Cleared Date: 02-NOV-1987

BK880013-0 Stericon Inc.
2315 Gardner Road.
Broadview, IL 60153
Trade Name: RCM-10 Pediatric Sized Freezing Bag
Cleared Date: 09-NOV-1988

BK920022-0 Stericon Inc.
2315 Gardner Road.
Broadview, IL 60153
Trade Name: MB-30 Empty Plastic Containers
Cleared Date: 03-JUN-1993

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
Trade Name: SynGenX-1000
Cleared Date: 12-JUL-2013

BK120067-0 SysLogic, Inc.
375 Bishops Way, Suite 105
Brookfield, WI 53005
Trade Name: iTrace for Blood Centers -
Cleared Date: 14-SEP-2017

BK960034-0  SysTec Computer Associates, Inc.
738 Smithtown Bypass
Smithtown, NY 11787
Trade Name: Lifetec Comm. Blood Center
System-Rev 2.10
Cleared Date: 28-JUL-1998

BK990003-0  SysTec Computer Associates, Inc.
28 North Country Road
Mt. Sinai, NY 11766
Trade Name: LifeTec - 2.20
Cleared Date: 30-JUL-1999

BK040026-0  SysTec Computer Associates, Inc.
28 North Country Road
Mt. Sinai, NY 11766
Trade Name: LifeTec Donor Verification and Collection System (DOVAC) - 1.00
Cleared Date: 21-OCT-2004

BK060032-0  SysTec Computer Associates, Inc.
28 North Country Road
Mt. Sinai, NY 11766
Trade Name: LifeTec Elite - 1.0
Cleared Date: 15-AUG-2006

BK080067-0  Sysmex America, Inc.
One Nelson C. White Parkway
Mundelein, IL 60060
Trade Name: Sysmex XE-2100D and XS-1000i
Cleared Date: 08-SEP-2009

BK120076-0  TERUMO BCT
10811 W. Collins Ave
Lakewood, CO 80215-4440
Trade Name: Spectra Optia Apheresis System
Cleared Date: 25-FEB-2013

BK130031-0  TERUMO BCT
10811 W. Collins Ave
Lakewood, CO 80215-4440
Trade Name: Spectra Optia Apheresis System
Cleared Date: 25-JUL-2013

BK130065-0  TERUMO BCT
10811 W. Collins Ave
Lakewood, CO 80215-4440
Trade Name: Spectra Optia Apheresis System
Cleared Date: 16-JAN-2014

BK130080-0  TERUMO BCT
10811 W. Collins Ave
Lakewood, CO 80215-4440
Trade Name: Trima Accel System, Version 6.2
Cleared Date: 19-MAR-2014

BK140151-0  TERUMO BCT
10811 W. Collins Ave
Lakewood, CO 80215-4440
Trade Name: Spectra Optia Apheresis System
Cleared Date: 13-AUG-2014
BK150251-0 TERUMO BCT
10811 W. Collins Ave
Lakewood, CO 80215-4440
Trade Name: Spectra Optia Apheresis System
Cleared Date: 16-JUL-2015

BK160116-0 TERUMO BCT
10811 W. Collins Ave
Lakewood, CO 80215-4440
Trade Name: Trima Accel Automated Blood Collection System
Cleared Date: 23-DEC-2016

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.
421 Church Street NE. Suite F
Vienna, VA 22180
Trade Name: Quality Donor System - v2.1
Cleared Date: 16-JUL-2007

BK980021-0 Talon Medical, Ltd.
18160 Highway 281 N
Suite 108  
San Antonio, TX 78232  
Trade Name: Cord-X System  
Cleared Date: 20-JAN-1999

BK050003-0 Tepnel Lifecodes Corporation  
550 West Avenue  
Stamford, CT 06902  
Trade Name: LIFECODES HLA-A Typing Kit for use with Luminex 100, LIFECODES HLA-B Typing Kit for use with Luminex 100, HLA-C Typing Kit for use with Luminex 100, LIFECODES HLA-DQB Typing Kit for use with Luminex 100 and LIFECODES HLA-DRB Typing Kit for use with Luminex 100  
Cleared Date: 18-JUL-2005

BK080050-0 Tepnel Lifecodes Corporation  
550 West Avenue  
Stamford, CT 06902  
Trade Name: LIFECODES HLA Typing Kits (HLA-A, B, C, DQB, DRB, DRB1) for use with Luminex  
Cleared Date: 13-NOV-2008

BK090018-0 Tepnel Lifecodes Corporation  
550 West Avenue  
Stamford, CT 06902  
Trade Name: LIFECODES Evolution Software, version 1.0  
Cleared Date: 04-JUN-2009

BK010006-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Trima Automated Blood Component Collection System  
Cleared Date: 27-FEB-2002  
Cleared Under Gambro BCT, Inc

BK010037-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Platelet collection sets for the COBE Spectra Apheresis System and the Trima Automated Blood Component Collection System.  
Cleared Date: 24-SEP-2003  
Cleared Under Gambro BCT, Inc

BK010046-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Trima Automated Blood Collection System (Single Stage)  
Cleared Date: 18-SEP-2002  
Cleared Under Gambro BCT, Inc

BK010050-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Trima Automated Blood Collection System
Cleared Date: 18-SEP-2002
Cleared Under Gambro BCT, Inc

BK020015-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System, Independent Solution
Cleared Date: 15-JUL-2002
Cleared Under Gambro BCT, Inc

BK020041-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: COBE Spectra Apheresis System/Blood component disposable collection sets for apheresis
Cleared Date: 23-APR-2003
Cleared Under Gambro BCT, Inc

BK030021-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System - 2.1
Cleared Date: 01-MAY-2003
Cleared Under Gambro BCT, Inc

BK030083-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel
Cleared Date: 14-JAN-2004
Cleared Under Gambro BCT, Inc

BK040069-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Automated Blood Component Collection System - Blood Component Sampling Accessory
Cleared Date: 28-OCT-2004
Cleared Under Gambro BCT, Inc

BK040086-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: COBE Spectra Apheresis System & Trima Automated Blood Component Collection System
Cleared Date: 15-MAR-2005
Cleared Under Gambro BCT, Inc

BK070001-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System - 3.0
Cleared Date: 27-JUN-2007
Cleared Under Gambro BCT, Inc

BK070066-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System, Version 3.0 with Medical Review Module
Cleared Date: 13-DEC-2007
Cleared Under Gambro BCT, Inc

BK080010-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: The Atreus Whole Blood Processing System
Cleared Date: 27-JUN-2008
Cleared Under Gambro BCT, Inc

BK080029-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel Automated Blood Component Collection System
Cleared Date: 18-MAY-2010
Cleared Under Gambro BCT, Inc

BK140104-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System Version 3.2
Cleared Date: 01-APR-2014

BK140158-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel System Version 6.4
Cleared Date: 29-AUG-2014

BK140180-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Model 81000 Trima Accel System Mobile Pro Package
Cleared Date: 05-NOV-2014

BK140191-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Spectra Optia Apheresis System
Cleared Date: 09-MAR-2015

BK150228-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System - 4.0
Cleared Date: 22-SEP-2015

BK150269-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel System
Cleared Date: 06-AUG-2015

BK150321-0 Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel System
Cleared Date: 16-OCT-2015

BK160082-0 Terumo BCT, Inc
BK160108-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: T-Cuff
Cleared Date: 19-AUG-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
Cleared Date: 17-AUG-2018

BK180258-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: Vista Information System
Cleared Date: 18-JAN-2019

BK190332-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: Trima Accel Blood Collection System
Cleared Date: 22-MAY-2019

BK190333-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: TOMEs - 7
Cleared Date: 03-DEC-2019

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 ABD Typing Kit
Cleared Date: 22-MAR-2007

BK080039-0  Texas BioGene, Inc.
635 Presidential Drive
Richardson, TX 75081
Trade Name: Morgan HLA SSP ABCRDQ 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 95741
Trade Name: AXP II AutoXpress Platform
Cleared Date: 14-NOV-2018

BK960072-0  Thermogenesis
3146 Gold Camp Drive
Suite 206
Rancho Cordova, CA 95670-6022
Trade Name: CryoSeal System
Cleared Date: 12-FEB-1999

BK960074-0  Thermogenesis
3146 Gold Camp Drive
Suite 206
Rancho Cordova, CA 95670-6022
Trade Name: HemoMatic Blood Collection Monitor
Cleared Date: 03-APR-1997

BK030011-0  Thermogenesis
3146 Gold Camp Drive
Suite 206
Rancho Cordova, CA 95670-6022
Trade Name: ThermoGenesis Thawer
Cleared Date: 10-JUN-2003

BK070006-0  Thermogenesis
2711 Citrus Road
Rancho Cordova, CA 95742
Trade Name: AXP AutoXpress Platform
Cleared Date: 05-OCT-2007

BK100066-0  Thermogenesis
2711 Citrus Road
Rancho Cordova, CA 95742
Trade Name: ThermoGenesis Res-Q60 PRP Device
Cleared Date: 27-MAY-2011

BK900017-0 Thermopol Inc.
2481 B Delta Ln.
Elk Grove Village, IL 60007
Trade Name: Solid State Portable Refrigerator
Cleared Date: 30-AUG-1990

BK940038-0 Thomson & Neilsen, Ltd.
1050 Baxter Road
Ottawa, Ontario, Canada, Canada
Trade Name: Blood Irradiator Dosimetry System
TN-ID-50
Cleared Date: 18-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

BK190363-0 Timestrip UK Ltd.
22 Friars Street
Sudbury,
Suffolk United Kingdom CO102AA
Trade Name: Timestrip Blood Temp 10
Cleared Date: 22-JUL-2019

BK850007-0 Trayser, Inc.
P.O. Box 83
Cabin John, MD 20818
Trade Name: Trayser DR/DQ Typing Tray Kit
Cleared Date: 25-APR-1985

BK030066-0 Tyco Healthcare
15 Hampshire Street
Mansfield, MA 02048
Trade Name: Kendall LIFETRACE Umbilical Blood Collection Kit
Cleared Date: 03-NOV-2003

BK070037-0 Typenex Medical LLC
303 East Wacker Drive
Suite 311
Chicago, IL 60601
Trade Name: TypeSafe Segment Dispenser
Cleared Date: 05-OCT-2007

BK150351-0 Typenex Medical LLC
303 East Wacker Drive
Suite 311
Chicago, IL 60601
Trade Name: Typesafe 2.0 Segment Piercing Device (Model Number SP0201QD & SP0201QM)
Cleared Date: 28-DEC-2015

BK820012-0 UCLA Tissue Typing Laboratory
1000 Veteran Avenue
Los Angeles, CA 90024
Trade Name: HLA Typing Tray
Cleared Date: 04-MAR-1983
Trade Name: FIBRINET (R) Autologous PRP System
Cleared Date: 01-AUG-2012
Cleared Under Cascade Medical Enterprises, LLC

Trade Name: Trugene HIV-1 Genotyping Kit and Open Gene DNA Sequencing System
Cleared Date: 24-APR-2002

Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 07-NOV-2002

Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 14-MAR-2003

Trade Name: ENDOTOXIN CHALLENGE VIALS
Cleared Date: 09-AUG-1991

Trade Name: Toxinometer ET-201
Cleared Date: 10-FEB-1987

Trade Name: Safe-T-Vue Irreversible Temperature Indicator
Cleared Date: 12-MAY-1992

Trade Name: Safe Trace
Cleared Date: 14-APR-1997

Trade Name: SafeTrace TX, version 1.0
Cleared Date: 29-JAN-1999

Trade Name: ElDorado Donor Doc - 1.0.0
Cleared Date: 23-MAY-2007
BK070064-0  Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: 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: El Dorado 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 El Dorado 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 El Dorado 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