Currently Cleared CBER 510(k)s by Applicant As of 31-OCT-2019

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

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

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

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

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

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

BK060051-0 5D Information Management
Suite 500, 10025 - 102A Avenue
Edmonton, Alberta Canada T5J 2Z2
Trade Name: HaemoConnect (eLynx) - 1.0.0
Cleared Date: 06-MAR-2008

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

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

BK050005-0 ALBA Bioscience Limited (doing business as Quotient)
21 Ellen's Glen Road
Liberton, Edinburgh
EH17 7QT
Scotland, UNITED KINGDOM, United Kingdom EH17 7QT
Trade Name: Quant-Rho FITC Anti-D for Fetal Cell Assay
Cleared Date: 27-SEP-2005
Cleared Under ALBA Bioscience

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

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

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

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

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

BK140144-0 ALBA Bioscience Limited (doing business as Quotient)
21 Ellen's Glen Road
Liberton, Edinburgh
EH17 7QT
Scotland, UNITED KINGDOM, United Kingdom EH17 7QT
Trade Name: ALBAzyme(TM) Papain Solution Kit
Cleared Date: 17-SEP-2014
BK140208-0 ALBA Bioscience Limited (doing business as Quotient)
21 Ellen’s Glen Road
Liberton, Edinburgh
EH17 7QT
Scotland, UNITED KINGDOM, United Kingdom EH17 7QT
Trade Name: ALBAcyte® C3 Coated Red Blood Cells
Cleared Date: 04-MAR-2015

BK150217-0 ALBA Bioscience Limited (doing business as Quotient)
21 Ellen’s Glen Road
Liberton, Edinburgh
EH17 7QT
Scotland, UNITED KINGDOM, United Kingdom EH17 7QT
Trade Name: ALBAsure® QC Kit
Cleared Date: 01-APR-2015

BK150246-0 ALBA Bioscience Limited (doing business as Quotient)
21 Ellen’s Glen Road
Liberton, Edinburgh
EH17 7QT
Scotland, UNITED KINGDOM, United Kingdom EH17 7QT
Trade Name: ORTHO(TM) Sera Papain
Cleared Date: 20-OCT-2015

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

BK870009-0 ARK-Bio-Medical Canada Corp.
#671 Rustico Road
Winsloe, Canada C1E 1Z2
Trade Name: WesLabs Model 601
Cleared Under Rush Enterprises, Inc.
Cleared Date: 15-NOV-1989

BK900012-0 Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-3500
Trade Name: Abbott Anti-HBs Panel
Cleared Date: 11-OCT-1990

BK950046-0 Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-3500
Trade Name: Abbott CMV Total AB EIA
Cleared Date: 22-DEC-1995

BK950048-0 Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-3500
Trade Name: Abbott Apheresis Results Tracking System/AARTS
Cleared Date: 24-JUN-1998

BK950052-0 Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-3500
Trade Name: Abbott DMS II Data Management System
Cleared Date: 12-AUG-1998
Trade Name: ABBOTT PRISM System
Cleared Date: 14-JUN-1999

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

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

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

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

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

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

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

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

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

Trade Name: AcroMetrix Corporation

Trade Name: ViroSure Multi-Marker
Cleared Date: 11-FEB-1998

BK040060-0 AcroMetrix Corporation
6058 Egret Court
Benicia, CA 94510
Trade Name: VeriSure Pro External Quality Controls
Cleared Date: 03-MAY-2005

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

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

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

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

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

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

BK160045-0 Alliance Partners LLC
14206 Northbrook Drive
San Antonio, TX 78232
Trade Name: Cyclone Platelet Rich Plasma (PRP) Concentrating System
Cleared Date: 04-NOV-2016

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

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

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

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

BK860014-0 Alpha Therapeutic Corporation
5555 Valley Boulevard
Los Angeles, CA 90032
Trade Name: JMS Double Blood Collection Pack
Cleared Date: 04-JUN-1986

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

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

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

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

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

BK960040-0 American Red Cross
Diagnostic Manufacturing Division
2025 E Street NW
Washington, DC 20006
Trade Name: NBCS 1.1
Cleared Date: 28-FEB-1997
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 Bromelain
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%
Cleared Date: 03-MAR-1986

Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name: Bovine Albumin 30%
Cleared Date: 03-MAR-1986
Amtec Diagnostics International Inc.
1107 IH-45 South
Conroe, TX 77305
Trade Name: Amtec Anti-A1 Lectin
Cleared Date: 16-JUN-1986

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

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

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

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

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

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

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

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

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

Applied Science, Inc.
964-B Golden Gate Terrace
Grass Valley, CA 95945
Trade Name: Hemoflow Model 400 with Data
Applied Sciences, Inc.
964-B Golden Gate Terrace
Grass Valley, CA 95945
Trade Name: HemoFlow Donor Monitor
Cleared Date: 16-JUL-1999

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

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

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

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

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

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

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

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

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

BK910017-0 Assoc. of Cape Cod
P.O. Box 224
Woods Hole, MA 02543
Trade Name: Control Standard Endotoxin/Pepyrogenation 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: ENDORRET Kit
Cleared Date: 09-DEC-2015

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

BK970004-0 BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name: ACCURUN155
Cleared Date: 23-APR-1999
Cleared Under Boston Biomedica, Inc.
B030027-0  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  

B050062-0  BD Biosciences  
2350 Qume Drive  
San Jose, CA 95131-1807  
Trade Name: BD HLA-B27 kit  
Cleared Date: 27-OCT-2005  

B050073-0  BD Biosciences  
2350 Qume Drive  
San Jose, CA 95131-1807  
Trade Name: BD HLA-B27 System  
Cleared Date: 16-FEB-2006  

B110037-0  BD Biosciences  
2350 Qume Drive  
San Jose, CA 95131-1807  
Trade Name: BD Stem Cell Enumeration Kit  
Cleared Date: 19-OCT-2011  

B150307-0  BD Biosciences  
2350 Qume Drive  
San Jose, CA 95131-1807  
Trade Name: BD FACSVia System with the BD Leucocount reagent Assay  
Cleared Date: 16-SEP-2016  

B00024-0  BECTON DICKINSON VACUTAINER Systems  
1 Becton Drive  
Franklin Lakes, NJ 07417  
Trade Name: Plasma Preparation Tube - PPT  
Cleared Date: 10-AUG-1998  

B080011-0  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  

B820008-0  BMT Incorporated  
7315 Hazeltine Boulevard  
Excelsior, MN 55331  
Trade Name: BMT Model 24 Bloodmixer  
Cleared Date: 22-OCT-1982  

B940031-0  Bard Radiology  
10115 Highway 142  
Covington, GA 30209  
Trade Name: True-Pulse Infusion Catheter  
Cleared Date: 27-APR-1995  

B100063-0  Barkey GmbH & Co KG  
Gewerbestrasse 8
Trade Name: plasmatherm
Cleared Date: 14-SEP-2017

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

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

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

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

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

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

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

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

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

BK020059-0 Baxter Healthcare Corporation
25212 West ILL Route 120
RoundLake, IL 60073
Trade Name: ALYX Component Collection System
Cleared Date: 23-JAN-2003
BK170033-0  Baxter Healthcare Corporation
32650 North Wilson Rd
Round Lake, IL 60073
Trade Name: DUO Set
DULO Set A
DUPLOCATH Application Catheter
DUPLOJECT
Cleared Date: 24-JUL-2017

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

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

BK050035-0  Bayer Healthcare Diagnostics Division
P.O. Box 2466
Berkeley, CA 94703-5828
Trade Name: TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 20-SEP-2005

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

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

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

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

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

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

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

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

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

BK950068-0
Becton, Dickinson & Company
1 Becton Drive, MC 300
Franklin Lakes, NJ 07417-1885
Trade Name: CMV Scan Card Test
Cleared Date: 22-DEC-1995

BK040030-0
Becton, Dickinson & Company
1 Becton Drive, MC 300
Franklin Lakes, NJ 07417-1885
Trade Name: BD Vacutainer Plus Plastic Serum Tubes with Clot Activator
Cleared Date: 05-MAY-2004

BK050036-0
Becton, Dickinson & Company
1 Becton Drive, MC 300
Franklin Lakes, NJ 07417-1885
Trade Name: BD Vacutainer Plus K2EDTA Tubes
BD Vacutainer Plus Serum Tubes
BD Vacutainer SST Glass Tubes
BD Vacutainer SST II Advance Tubes
BD Vacutainer SST Plus Tubes
Cleared Date: 24-FEB-2006

BK060046-0
Becton, Dickinson & Company
1 Becton Drive, MC 300
Franklin Lakes, NJ 07417-1885
Trade Name: Bd.id Patient Identification System for Transfusion Management - V7.00
Cleared Date: 13-FEB-2007

BK180211-0
Becton, Dickinson & Company
7 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™
Cleared Date: 16-DEC-2015
Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, Germany 63303
Trade Name: IH-1000 (Model # 001100)
Cleared Date: 05-MAY-2017

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

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

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

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

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

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

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

Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, Germany 63303
Trade Name: TANGO Infinity
Cleared Date: 01-MAY-2018

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

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

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

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

BK190312-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, Germany 63303
Trade Name: TANGO infinity
Cleared Date: 23-APR-2019

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

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

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

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

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

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

BK150347-0 BioLife Plasma Services L.P. - Baxalta US Inc
440 N. Fairway Drive, 2W - 141
Vernon Hills, IL 60061
Trade Name: Lookback Notification System
(LNS), Version 1.0
Cleared Date: 12-FEB-2016

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK070003-0  Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name: GPS 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.
Trade Name: CEQer RBC Assay
Cleared Date: 18-SEP-1998

Biometric Imaging, Inc.
1025 Terra Bella Avenue
Mountain View, CA 94043

Trade Name: CEQer PRP Assay
Cleared Date: 18-SEP-1998

Biometric Imaging, Inc.
1025 Terra Bella Avenue
Mountain View, CA 94043

Trade Name: STELLer CD34 Assay
Cleared Date: 18-AUG-1998

Biopool International, Inc.
1230 Wilson Drive
West Chester, PA 19380-4254

Trade Name: sLiDe Chek
Cleared Date: 11-JUN-1999

Biosafe SA
Route du Petit-Eysins
Eysins, Vaud Switzerland 1262

Trade Name: CryoSC Freezing Bag
Cleared Date: 22-MAR-2010

Biosafe SA
Route du Petit-Eysins
Eysins, Vaud Switzerland 1262

Trade Name: Sepax Cell Separation and single use kits
Cleared Date: 28-OCT-2011

Biosafe SA
Route du Petit-Eysins
Eysins, Vaud Switzerland 1262

Trade Name: Sepax Cell Separation System and Single Use Kits
Cleared Date: 13-FEB-2015

Biotech Research Laboratories, Inc.
1600 East Gude Drive
Rockville, MD 20850

Trade Name: Run Control for HBsAg Assay
Cleared Date: 25-JAN-1985

Biotechnology Institute, SL.
C/Leonardo Da Vinci 14B, 1B.
01510 M inano (Alava)
Alava, Spain 01510

Trade Name: Endoret Kit
Secondary Product Code: FMI, GKT
Cleared Date: 01-FEB-2010

Biotest AG
Postfach 10 20 40
D-63266 Dreieich, Germany

Trade Name: TANGO Automated Blood Bank Analyzer System, Version 3.0 Service Pack 4
Cleared Date: 17-JAN-2007

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

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

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

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

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

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

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

BK080012-0 Biotest Medical Diagnostics GmbH
P.O. Box 10 21 50
63267 Dreieich, Germany
Trade Name: (1) Seraclone Control ABO+Rh
(2) Coombscell-E
(3) MLB2
Cleared Date: 23-JUL-2008

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

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

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

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

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

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

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

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

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

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

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

BK930034-0 Blackhawk BioSystems, Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name: Virotrol III
Cleared Date: 27-JUL-1994

BK950011-0 Blackhawk BioSystems, Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name: Virotrol III
Cleared Date: 27-JUL-1994

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

BK000041-0 Blackhawk BioSystems, Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name: Virotrol III
Cleared Date: 03-OCT-1997

BK060052-0 Blackhawk BioSystems, Inc.
12945 Alcosta Blvd.
San Ramon, CA 94583
Trade Name: Virotrol III
Cleared Date: 03-OCT-1997

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

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

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

BK050013-0 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
Trade Name: BBCS Mobile Application - 5.0M
Cleared Date: 01-JUN-2005

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

BK120028-0 Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
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

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

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

BK080058-0  CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name: Trima Accel Automated Blood Component Collection System
Cleared Date: 25-NOV-2008
BK090003-0 CaridianBCT
10811 W. Collins Avenue
Lakewood, CO 80215-4498
Trade Name: Trima Accel System
Cleared Date: 16-FEB-2010

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK150021-0  Celling Biosciences, Inc.
93 Red River St.
Austin, TX 78701
Trade Name: Circle Biologics Autologous Platelet Separator (APS) System
Cleared Date:  09-JUN-2015
BK860025-0  Cetus Corporation  
1400 53rd Street  
Emeryville, CA 94608  
Trade Name: Pro Group System  
Cleared Date: 27-APR-1987

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK100014-0 Circle Biologics, Inc.
3650 Annapolis Lane, Suite 105
Minneapolis, MN 55447
Trade Name: Autologous Fluid Concentrator (AFC) System
Changed with 6/25/10 Submission to: "Autologous Platelet Concentrator (APC) (TM) System"
Cleared Date: 09-JUL-2010
Cleared Under Circle Biologic, LLC

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

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

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

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

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

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

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

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

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

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

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

BK950030-0 Cobe Laboratories, Inc.
1185 Oak Street
Lakewood, CO 80215
Trade Name: COBE Spectra Extended Life Platelet Set
Cleared Date: 15-FEB-1996
BK970007-0  Community Bio-Resources, Inc.
                  2197 Parkway Lake Drive
                  Hoover, AL 35244
                  Trade Name: Donor Information System - 1.0
                  Cleared Date: 09-APR-1997

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

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

BK920006-0  Connaught Laboratories Limited
                  Discovery Drive
                  Swiftwater, PA 18370
                  Trade Name: CONTINENTAL REFRIG. BLD.BNK. MODEL C-BBRA-15
                  Cleared Date: 17-JUL-1992

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

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

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

BK850008-0  Cooper Biomedical
                  1 Technology Court
                  Malvern, PA 19355
                  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 ("APIC") System
Cleared Date: 17-JAN-2014

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

BK000022-0  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
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
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Trade Name: DG Gel 8 Neutral Gel

Trade Name: Grifols Diluent

Trade Name: DG Spin

Trade Name: DG THERM

Trade Name: WADiana(R) Compact

Trade Name: Erytra(R)

Trade Name: DG Reader

Trade Name: DG Gel(R) 8 Neutral

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 Efleksis
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

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
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<th>BK Code</th>
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<td>BK960041-0</td>
<td>Dynamic Healthcare Technologies, Inc.</td>
<td>101 Southhall Lane, Suite 210 Maitland, FL 32751</td>
<td>Transfusion Service Mgr.</td>
<td>16-DEC-1997</td>
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<td>BK840004-0</td>
<td>Dynatech Laboratories, Inc.</td>
<td>900 Slaters Lane, Alexandria, VA 22314</td>
<td>MicroBBank 220 Automated Microplate Reader</td>
<td>18-MAY-1984</td>
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<td>BK850013-0</td>
<td>Dynatech Laboratories, Inc.</td>
<td>900 Slaters Lane, Alexandria, VA 22314</td>
<td>MicroBank System</td>
<td>08-OCT-1985</td>
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<td>BK840003-0</td>
<td>E.I. duPont de Nemours &amp; Company</td>
<td>900 Slaters Lane, Alexandria, VA 22314</td>
<td>DuPont SCD</td>
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<td>BK840018-0</td>
<td>EK Industries, Inc.</td>
<td>411 Kay Avenue, Addison, IL 60101</td>
<td>Copper Sulfate Solution (for women)</td>
<td>11-DEC-1984</td>
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<td>BK840019-0</td>
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<td>411 Kay Avenue, Addison, IL 60101</td>
<td>Copper Sulfate Solution (for men)</td>
<td>11-DEC-1984</td>
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<td>BK170138-0</td>
<td>ETHICON Inc.</td>
<td>Route 22 West, P.O. Box 151 Somerville, NJ 08876</td>
<td>EVICEL™ Laparoscopic Airless Spray Accessory (35 cm Rigid)</td>
<td>26-JAN-2018</td>
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<td>BK180287-0</td>
<td>ETHICON Inc.</td>
<td>Route 22 West, P.O. Box 151 Somerville, NJ 08876</td>
<td>VISTASEAL Airless Spray Accessory</td>
<td>10-APR-2019</td>
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<td>BK190324-0</td>
<td>ETHICON Inc.</td>
<td>Route 22 West, P.O. Box 151 Somerville, NJ 08876</td>
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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: Fenwal 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
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

Trade Name: Optipress™ Automated Blood Component
Cleared Date: 18-MAY-1994
Cleared Under Baxter Healthcare Corporation

Trade Name: Ex Storage PL 732 Containers w/ Sepacell Filter for Leukocytes Reduced Platelets
Cleared Date: 27-JUL-1994
Cleared Under Baxter Healthcare Corporation

Trade Name: Accessory Weight Scale for Medical Purposes
Cleared Date: 05-JUL-1994
Cleared Under Baxter Healthcare Corporation

Trade Name: Storage Containers for CS-3000 Apheresis Kit
Cleared Date: 27-DEC-1994
Cleared Under Baxter Healthcare Corporation

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

Trade Name: Sepacell R-2000 Prestorage Leukocyte Reduction Set for Red Blood Cells
Cleared Date: 14-FEB-1995
Cleared Under Baxter Healthcare Corporation

Trade Name: CS-3000 Plus (mononeuclear cells)
Cleared Date: 12-NOV-2002
Cleared Under Baxter Healthcare Corporation
BD950016-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Pall BP4 Leukocyte Reduction Set for RBC
Cleared Date: 20-SEP-1995
Cleared Under Baxter Healthcare Corporation

BD950023-0 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

BD960005-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Amicus Separator
Cleared Date: 19-DEC-1996
Cleared Under Baxter Healthcare Corporation

BD960083-0 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.

BD980041-0 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

BD990009-0 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

BD990039-0 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

BD000047-0 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

BD010016-0 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

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
BK100056-0 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: Autopheresis-C Plasmapheresis system
Cleared Date: 16-NOV-2010

BK110025-0 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: ALYX Component Collection System
Cleared Date: 07-DEC-2010

BK110030-0 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: Software, Blood Ban, Stand Alone
Cleared Date: 22-AUG-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 Drive
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
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: PLASMALNK
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.
Trade Name: Alyx Component Collection System (Alyx Classic)
Alyx Component Collection System (Alyx by Fenwal)
Alyx Plasma Kit
Cleared Date: 01-NOV-2013

Trade Name: Bone Marrow Collection Kit and Stand
Cleared Date: 09-JUN-2016

Trade Name: Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters
Bone Marrow Collection Stand
Cleared Date: 24-JUL-2017

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

Trade Name: Aurora Xi Plasmapheresis System
Cleared Date: 21-SEP-2016

Trade Name: Aurora Xi Plasmapheresis System/Aurora Xi/Aurora Xi system/Aurora Xi Software Version 1.1
Cleared Date: 25-AUG-2017

Trade Name: DXT Data Management System
Cleared Date: 26-SEP-2017

Trade Name: DXT Data Management System - 3.1
Cleared Date: 14-AUG-2018

Trade Name: Glycerolyte 57 Solution, 400 mL
Glycerolyte 57 Solution, 500 mL
Cleared Date: 03-DEC-2018
BK180268-0 Fresenius Kabi AG
Three Corporate Dr
Lake Zurich, IL 60047
**Trade Name:** Aurora XI Plasmapheresis System/Aurora XI System/Aurora XI - 1.2
**Cleared Date:** 02-NOV-2018

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

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

BK190368-0 Fresenius Kabi AG
Else-Kroner-Strasse 1
Bad Homburg, Germany 61346
**Trade Name:** Aurora Plasmapheresis System/Aurora 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
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
Trade Name: Olympus PK CMV-PA System & Controls
Cleared Date: 28-OCT-1998

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

Trade Name: Olympus PK TP System
Cleared Date: 21-FEB-2003

Trade Name: Olympus PK® TP Reagent System
Cleared Date: 25-JUN-2007

Trade Name: Olympus PK CMV-PA Test System and Controls
Olympus PK7300 Automated Blood Bank Analyzer
Cleared Date: 20-SEP-2007

Trade Name: Olympus PK TP System Reactive Control
Cleared Date: 29-NOV-1995

Trade Name: AM-4
Cleared Date: 29-SEP-1994

Trade Name: L Fusion Bags for Warming Blood/Plasma w/ ANIMEC
Cleared Date: 27-DEC-1994

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
Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092

Trade Name: Gamma Micro-U Accessory Equipment
Cleared Date: 20-MAR-1986

Trade Name: Gamma Micro-U Coombs Wash Solution
Cleared Date: 20-MAR-1986

Trade Name: Gamma Micro-U Enhancement Reagent
Cleared Date: 20-MAR-1986

Trade Name: Gamma N-HANCE
Cleared Date: 26-AUG-1986

Trade Name: GammaZyme-B
Cleared Date: 25-AUG-1988

Trade Name: Gamma-clone Control
Cleared Date: 26-OCT-1990

Trade Name: Gamma Peg
Cleared Date: 24-MAR-1992

Trade Name: Gamma RQC-Kit
Cleared Date: 16-NOV-1993

Trade Name: Coombs Control Cells (EIgG) Strong
Cleared Date: 23-OCT-1996

Trade Name: Coombs Control Cells (EIgG) Weak
Cleared Date: 23-OCT-1996

Trade Name: Coombs Control Cells (EIgG) Weak
Cleared Date: 23-OCT-1996
Withings and Trade Name: LIFECODES HLA-C eRES Typing Kit for use with Luminex

Cleared Date: 21-NOV-2012

Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186

Trade Name: Antibody Monitoring System Class I and Class II (AMS1 and AMS1+2)

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

Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186

Trade Name: Lifecodes LifeScreen: A Luminex 100 Screening Assay for the Detection of IgG Antibodies to HLA Class I and Class II Molecules of Human Origin

Cleared Date: 16-JUL-2004
Cleared Under GTI, INC

Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186

Trade Name: Lifecodes LifeScreen: A Luminex 100 screening assay for the qualitative detection of IgG panel reactive antibodies (PRA) to HLA Class I molecules

Cleared Date: 16-JUL-2004
Cleared Under GTI, INC

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

Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186

Trade Name: GranType(TM)

Cleared Date: 02-MAR-2006
Cleared Under GTI, INC

Gen-Probe GTI Diagnostics
20925 Crossroads Circle
Waukesha, WI 53186

Trade Name: MICROAMS

Cleared Date: 28-JUL-2006
Cleared Under GTI, INC

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

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

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

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

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

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

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

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

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

BK930031-0 Genetic Systems Corporation
3005 First Avenue
Seattle, WA 98121
Trade Name: Expresso Cartridge Software for Blood Virus Applications
Cleared Date: 24-FEB-1994
BK860022-0 Genetic Testing Institute
1701 W. Wisconsin Avenue, Suite 429
Milwaukee, WI 53233
Trade Name: GTI-60 HLA Typing Trays
GTI-72 HLA Typing Trays
GTI-96 HLA Typing Trays
Cleared Date: 24-FEB-1987

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

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

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

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

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

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

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

BK000015-0 Genetic Testing Institute
150 N. Patrick Blvd.
Brookfield, WI 53045
Trade Name: Quick ID Solid Phase ELISA for detection of Panel Reactive HLA Class I IgG Antibodies (PRA)
Cleared Date: 17-OCT-2000
**BK000031-0** Genetic Testing Institute  
150 N. Patrick Blvd.  
Brookfield, WI 53045  
Trade Name: GTI-MACE (Modified Capture Elisa)  
Cleared Date: 29-JAN-2001

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

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

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

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

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

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

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

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

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

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

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

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

BK030032-0 Greiner Bio-One GmbH
4238 Capital Drive
Monroe, NC 28112
Trade Name: Vacuette EDTA K2 Tube
Cleared Date: 18-JUL-2003

BK040066-0 Greiner Vacuette North America, Inc.
4238 Capital Dr
Monroe, NC 28110
Trade Name: Greiner VACUETTE No Additive Evacuated Blood Collection Tubes and Serum Clot Activator Blood Collection Tubes
Cleared Date: 10-SEP-2004
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
Trade Name: Alpha Plasma Pooling Bottle II
Cleared Date: 08-SEP-1991

Trade Name: 705FTSPP/790F
Cleared Date: 16-SEP-1992

Trade Name: Plasma Collection System PCS2
Cleared Date: 02-SEP-1993

Trade Name: 790 Extended Storage Platelet Collection Set
Cleared Date: 16-NOV-1993

Trade Name: 791 A Fresh Frozen Plasma Collection Set (Latham Bowl)
Cleared Date: 16-NOV-1993

Trade Name: 791 Fresh Frozen Plasma Collection Set (Blow Molded Bowl)
Cleared Date: 16-NOV-1993

Trade Name: MCS Plus & Disp. Sets, List No. 890, 790, 791A, 791
Cleared Date: 12-JAN-1994

Trade Name: Red Cell and Plasma Apheresis Set/FOR USE WITH MCP PLUS
Cleared Date: 23-OCT-1995

Trade Name: Haemonetics RBC Apheresis Set for MCS+(NO. 831)
Cleared Date: 22-APR-1996

Trade Name: 791 Fresh Frozen Plasma Collection Set (Blow Molded Bowl)
Cleared Date: 16-NOV-1993
Trade Name: List #890F Extended Storage Plate Collection Set
Cleared Date: 09-JUN-1995

BK950007-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: ESP White Cell Filter (No. 790F)
Cleared Date: 28-JUN-1995

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

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

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

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

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

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

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

BK970029-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Alpha Plasma Pooling Bottle II (60-2227S)
Cleared Date: 07-JAN-1998
Cleared Under Alpha Therapeutic Corporation
Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: LN994CF
Cleared Date: 15-SEP-1998

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

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

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

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

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

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

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

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

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

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

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

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

Trade Name: Haemonetics LN994CF-BA Extended Storage Platelet and Plasma Apheresis Set with Leukocyte Reduction Filter, and 4 mL Sampling System.
Clearing Date: 29-MAR-2004

Trade Name: PCS2 Plasma Collection System
Clearing Date: 02-JUN-2004

Trade Name: Haemonetics MCS+8150 Apheresis System
Clearing Date: 12-JUL-2004

Trade Name: Haemonetics Model 215 Automated Glycerolization / Deglycerolization System
Clearing Date: 21-DEC-2004

Trade Name: ACP 215 Glycerolization / Deglycerolization System

Trade Name: Haemonetics LN994CF-CPP-BA Extended Storage Platelet and Plasma Apheresis Set.
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
Cleared Date: 05-FEB-2015

BK150287-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics MCS+ 8150 Apheresis System
Cleared Date: 28-JUL-2015

BK150292-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics PCS2 Plasma Collection System
Cleared Date: 28-JUL-2015

BK150360-0 Haemonetics Corporation
4925 Robert J Mathews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: SafeTrace Tx 3.12.0 Device
Cleared Date: 11-MAR-2016

BK160019-0 Haemonetics Corporation
4925 Robert J Mathews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: El Dorado Donor 4 Next Generation Donor Management Solution 1.0.0
Cleared Date: 17-MAY-2016

BK160052-0 Haemonetics Corporation
4925 Robert J Mathews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: InstaMatch 1.0.0
Cleared Date: 25-AUG-2016

BK170045-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: PCS 300 Plasma Collection System
Cleared Date: 25-JUL-2017

BK180185-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: PCS 300 Plasma Collection System
Cleared Date: 27-MAR-2018

BK180209-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Safe Trace Tx - 4.0.0
SafeTrace Tx
Cleared Date: 07-AUG-2018

BK080001-0 Haemonetics Corporation Software Solutions
1630 Industrial Park Street
Covina, CA 91722-9144
Trade Name: PCS2 Plasma Collection System Revision K software
Cleared Under Haemonetics Corporation
Cleared Date: 28-MAY-2008
<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Cleared Date</th>
<th>Cleared Under</th>
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<tbody>
<tr>
<td>Neocel System</td>
<td>22-MAY-1986</td>
<td>Miles, Inc.</td>
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<tr>
<td>Leukotrap System</td>
<td>05-AUG-1986</td>
<td>Cutter Biological</td>
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<td>Cutter PPP Harness</td>
<td>17-SEP-1986</td>
<td>Miles, Inc.</td>
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<td>Component Aliquot System</td>
<td>07-DEC-1987</td>
<td>Miles, Inc.</td>
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<tr>
<td>Blood Collection Unit w/o Anticoagulant</td>
<td>24-JUN-1987</td>
<td>Cutter Biological</td>
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<td>Phlebotomist Protection Device</td>
<td>27-JAN-1992</td>
<td>Miles, Inc.</td>
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<tr>
<td>Plasma Pooling Bag</td>
<td>13-APR-1993</td>
<td>Miles, Inc.</td>
</tr>
<tr>
<td>Plasma Sample Vial</td>
<td>20-SEP-1993</td>
<td>Miles, Inc.</td>
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Braintree, MA 02184
Trade Name: Modified Plasma Bag
Cleared Date: 27-SEP-2000
Cleared Under MEDSEP Corp.

BK020014-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Bacterial Detection System (BDS)
Cleared Date: 22-OCT-2002
Cleared Under Medsep Corporation

BK030082-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall eBDS
Cleared Date: 04-FEB-2004
Cleared Under Medsep Corporation

BK050015-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Leukotrap SC RC Filtration System
Cleared Date: 14-APR-2005
Cleared Under MEDSEP Corp.

BK050034-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Acrodose PL System, Platelet Pool and Store Set with eBDS
Cleared Date: 28-SEP-2005
Cleared Under Medsep Corporation

BK050074-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Acrodose PL System
Cleared Date: 26-JAN-2006
Cleared Under Medsep Corporation

BK050075-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall eBDS
Cleared Date: 20-DEC-2005
Cleared Under Medsep Corporation

BK060040-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Acrodose PL System, Platelet Pool and Store Set with in-line Leukocyte Reduction Filter
Cleared Date: 12-APR-2007
Cleared Under Medsep Corporation

BK060044-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Acrodose PL System, Platelet Pool and Store Set with eBDS
Cleared Date: 01-SEP-2006
Cleared Under Medsep Corporation

BK060045-0  Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Acrodose PL System, Platelet Pool and Store Set
Cleared Date: 01-SEP-2006
Cleared Under Medsep Corporation

BK060047-0  Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall eBDS
Cleared Date: 04-APR-2007
Cleared Under Medsep Corporation

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

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

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

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

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

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

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

BK000037-0  Harvest Technologies
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 iCASl
App iOSS
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 iCASl
App Android
Cleared Date: 29-JUL-2016

BK170141-0 Helmer Inc.
14400 Bergen Blvd.
Noblesville, IN 46060
Trade Name: UltraCW
UltraCW®II Automatic Cell Washing System
Cleared Date: 22-JAN-2018

BK820013-0 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name: Platelet Agitator
Cleared Date: 29-OCT-1982

BK820022-0 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name: Helmer Incubator-Agitator
Cleared Date: 03-JAN-1983

BK840027-0 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name: Helmer Platelet Agitator PF108
Helmer Platelet Agitator PF54
Cleared Date: 16-APR-1985
BK850014-0 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name: PLATELET FLATBED AGITATOR MODEL PF456
Cleared Date: 30-AUG-1985

BK850015-0 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name: Helmer Incubator Models PC1000
Helmer Incubator Models PC2000
Helmer Incubator Models PC3000
Cleared Date: 20-SEP-1985

BK850018-0 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name: Tube Stripper
Cleared Date: 21-OCT-1985

BK940051-0 Helmer Labs., Inc.
5415 Distribution Drive
Fort Wayne, IN 46825
Trade Name: Helmer Water Plasma Thawer
Cleared Date: 03-MAR-1995

BK020029-0 Helmer Labs., Inc.
15425 Herriman Boulevard
Noblesville, IN 46060
Trade Name: UltraCW (with Software version 3.13)
Cleared Date: 04-OCT-2002

BK890028-0 Hemagen Diagnostics, Inc.
9033 Red Branch Road
Columbia, MD 21045
Trade Name: Olympus PK CMV System
Cleared Date: 11-DEC-1989

BK940035-0 Hemagen Diagnostics, Inc.
9033 Red Branch Road
Columbia, MD 21045
Trade Name: Olympus PK TM CMV System & System Controls
Cleared Date: 15-JUL-1996

BK150300-0 Hemasoft Software SL
Antonio Lopez 249, 4 3A
Madrid, Spain 28041
Trade Name: e-Delphyn Blood management Software version 7.1.0.0
Cleared Date: 24-OCT-2015

BK950008-0 Hemasure, Inc.
140 Locke Drive
Marlborough, MA 01752
Trade Name: LeukoNet Pre Storage Leukodepletion Filtration System
Cleared Date: 28-JUN-1995

BK980014-0 Hemasure, Inc.
140 Locke Drive
Marlborough, MA 01752
Trade Name: HemaSure r|LS Pre-Storage
Leukoreduction Filtration System for Red Blood Cells
HemaSure r|LS Pre-Storage
Leukoreduction Filtration System with spike for Red Blood Cells
Cleared Date: 27-MAY-1999

BK070024-0 Hemerus Medical, LLC
5000 Township Parkway
Saint Paul, MN 55110
Trade Name: LEUKOSEP® HRC-600-C Leukocyte Reduction Filtration System for Red Blood Cells
Cleared Date: 23-AUG-2007

BK080031-0 Hemerus Medical, LLC
5000 Township Parkway
Saint Paul, MN 55110
Trade Name: HEMERUS LEUKOSEP HRC-600-C Leukocyte Reduction Filtration System for Red Blood Cells
Cleared Date: 11-SEP-2008

BK120022-0 Hemo bioscience
801 Capitola Drive, Suite 9
Research Triangle Park
Durham, NC 27713
Trade Name: C3 Control Cells
Cleared Date: 24-OCT-2012

BK140161-0 Hemo bioscience
801 Capitola Drive, Suite 9
Research Triangle Park
Durham, NC 27713
Trade Name: 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
Trade Name: HemoCue Low Hemoglobin Analyzing System
Cleared Date: 09-APR-2001

Trade Name: Donor Hemoglobin Checker System
Cleared Date: 17-APR-2003

Trade Name: HemoCue Donor Hb Checker Control
Cleared Date: 19-DEC-2003

Trade Name: Scansystem bacterial detection device
Cleared Date: 23-SEP-2004

Trade Name: Cryofuge 6000
Cleared Date: 05-NOV-1992

Trade Name: Inverness Blood Grouping System
Cleared Date: 20-SEP-1990

Trade Name: Inverness Automated Antibody Screening System
Cleared Date: 26-MAR-1993

Trade Name: Kelsea Clamp Needle Cover & Guide
Cleared Date: 28-OCT-1993

Trade Name: DoVac Elite 1.0
Cleared Date: 06-SEP-2012

Trade Name: DVac Elite v 2.0
Cleared Date: 09-APR-2014

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
LIFECODES HLA-DRB1 eRES SSO Typing Kit for use with Luminex
Cleared Date: 24-DEC-2013

BK150302-0 Immucor Transplant Diagnostics, Inc.
550 West Avenue
Stamford, CT 06902-6352
Trade Name: LIFECODES HLA-DPA1/B1 SSO Typing Kit
LIFECODES HLA-DQAI/B1 SSO Typing Kit
Cleared Date: 11-MAY-2016

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

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

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

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

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

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

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

BK830022-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ImmuAdd
Trade Name: Anti-A1 Lectin
Cleared Date: 07-NOV-1983

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

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

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

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

Trade Name: Modified Capture-P
Cleared Date: 08-DEC-1988

Trade Name: Capture-P Platelets Wash & Storage Solution
Cleared Date: 08-DEC-1988

Trade Name: Capture P Ready Screen Solid Phase Assay
Cleared Date: 03-MAY-1989

Trade Name: Capture-R Ready Screen (Pooled)

Cleared Date: 21-JUN-1990

BK890013-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R Ready-Screen (I&II)
Cleared Date: 21-JUN-1990

BK890014-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R Ready-Id
Cleared Date: 21-JUN-1990

BK890022-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Ficin Solution Reagent Set
Cleared Date: 26-JAN-1990

BK920033-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: pHix
Cleared Date: 21-SEP-1993

BK950017-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture S
Cleared Date: 24-OCT-1997

BK950029-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture - CMV
Cleared Date: 22-DEC-1995

BK960016-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Hemaglutination/Dilution Strips
Cleared Date: 04-JUN-1997

BK960017-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Modified Capture-R
Cleared Date: 30-JUN-1998

BK960018-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ABS QC Test System/ABS QC Test System Plus
Cleared Date: 21-JUL-1997
Trade Name: ABS2000
Cleared Date: 30-JUN-1998

Trade Name: Capture-R Control Cells
Cleared Date: 04-JUN-1997

Trade Name: Capture-S Solid Phase Assay
Cleared Date: 22-JUN-2000

Trade Name: ABS2000, Version 2 Software (2.05.00A and 2.05.00B)
Cleared Date: 03-JUL-2001

Trade Name: ABS2000 (version 1.00.30A SR-1)
Cleared Date: 16-FEB-2001

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

Trade Name: Capture-R Ready Indicator Red Cells
Cleared Date: 27-JAN-2003

Trade Name: Capture-R Control Cells
Cleared Date: 27-JAN-2003

Trade Name: Capture-R Control Cells
Cleared Date: 27-JAN-2003

Trade Name: Capture-R Control Cells
Cleared Date: 27-JAN-2003
BK040013-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Monoclonal Control
Cleared Date: 23-APR-2004

BK040014-0 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

BK040023-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Galileo QC Cell
Cleared Date: 22-APR-2004

BK040024-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: DAT Positive Control Cell
Cleared Date: 23-APR-2004

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

BK090057-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Galileo
Cleared Date: 09-JUL-2010

BK100001-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Galileo Neo
Cleared Date: 29-APR-2010

BK100033-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Galileo Neo
Cleared Date: 23-AUG-2010

BK110050-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Checkcell
Cleared Date: 03-OCT-2011

BK110067-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: FMH RapidScreen
Cleared Date: 22-MAY-2012

BK120016-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ImmuLINK, version 2.0
Cleared Date: 14-JUN-2012

BK120021-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: TPHA Screen
Cleared Date: 24-OCT-2012

BK150333-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ImmuLINK - V.1.7
Cleared Date: 19-NOV-2015

BK170067-0 Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30091-5625
Trade Name: Galileo Neo
Cleared Date: 19-JUL-2017
BK170132-0  Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Galileo Echo
Cleared Date: 27-APR-2018

BK170135-0  Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Echo Lumena
Cleared Date: 27-APR-2018

BK180220-0  Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Galileo Echo
Cleared Date: 17-JUL-2018

BK180243-0  Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: NEO Iris
Neo Iris - Version 3
Cleared Date: 07-NOV-2018

BK180247-0  Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Capture-CMV
Cleared Date: 20-NOV-2018

BK190337-0  Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Galileo NEO
Cleared Date: 19-JUN-2019

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
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

BK920035-0 International Specialty Products
1361 Alps Rd,
Wayne, NJ 07470
Trade Name: RAD-Sure 2500
Cleared Date: 01-APR-1993

BK120048-0 Intra-Lock International
6560 West Rogers Circle
Boca Raton, FL 33487
Trade Name: Intra-Spin System
Cleared Date: 28-JAN-2013

BK960054-0 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name: Jewett Models BPL13, BPL21, BPL25
Cleared Date: 08-AUG-1996

BK960073-0 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name: Models BBR17, BBR25, BBR37 & BBR55
Cleared Date: 30-OCT-1996

BK960089-0 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name: Jewett Model CT1
Cleared Date: 06-FEB-1997

BK970001-0 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name: Jewett Model CTF-1
Cleared Date: 16-APR-1997

BK970014-0 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name: Jewett Model BBWM3
Cleared Date: 18-JUL-1997

BK970028-0 Jewett Refrigerator Co., Inc.
2-18 Letchworth Street
Buffalo, NY 14213-1098
Trade Name: Jewett Model BPL55
Cleared Date: 15-OCT-1997

BK860037-0 Jouan, Inc.
Route 8, Box 1202; P.O. Box 2716
Winchester, VA 22601
Trade Name: Model LR5.22 centrifuge
Cleared Date: 15-DEC-1986

BK870001-0 Jouan, Inc.
Route 8, Box 1202; P.O. Box 2716
Winchester, VA 22601
Trade Name: Model GR 4.11 centrifuge
Cleared Date: 20-FEB-1987

BK890027-0 Jouan, Inc.
BK000003-0 Kawasaki Laboratories, Inc.
1900 K Street
Washington, DC 20006
Trade Name: Kawasaki Laboratories Phlebotomy
Cleared Date: 20-MAR-2000

BK170113-0 Kawasaki Laboratories, Inc.
Shinagawa Intercity Tower B
2-15-2 Konan
Minato-Ku
Tokyo, Japan 108-6109
Trade Name: Kawasaki Laboratories Blood
Drawing Kit (BDK) System - BK-64A
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
(Wireless) Option

Cleared Date: 17-JUL-2009

BK180232-0 MAK-SYSTEM SA International Group
10 Avenue de la Grande-Armeé
París 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 Armeé
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 Armeé
75017 Paris, France 75017
Trade Name: PROGESÁ - 4.4h
Cleared Date: 26-OCT-2007

BK080002-0 MAK-System
10 Avenue de la Grande Armeé
75017 Paris, France 75017
Trade Name: ePROGESÁ - 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
BK100043-0  MEDI WARE INFORMATION SYSTEMS, INC.
11711 West 79th Street
Lenexa, KS 66214
Trade Name: LifeTrak/Donor - 4.6.0
Cleared Date: 21-OCT-2010

BK100057-0  MEDI WARE INFORMATION SYSTEMS, INC.
11711 West 79th Street
Lenexa, KS 66214
Trade Name: LifeTrak/Lab and Distribution - 4.6.0
Cleared Date: 16-NOV-2010

BK100069-0  MEDI WARE INFORMATION SYSTEMS, INC.
11711 West 79th Street
Lenexa, KS 66214
Trade Name: LifeTrak/Plasma - 1.0.0
Cleared Date: 04-MAR-2011

BK980027-0  MEDSEP Corporation
330 Turnbull Canyon Road
City of Industry, CA 91745
Trade Name: Transfer/Freezing Bag Set
Cleared Date: 26-MAR-1999
Cleared Under MEDSEP Corp.

BK980030-0  MEDSEP Corporation
330 Turnbull Canyon Road
City of Industry, CA 91745
Trade Name: Medsep Freezing bag
Cleared Date: 29-AUG-1998
Cleared Under MEDSEP Corp.

BK980038-0  MEDSEP Corporation
330 Turnbull Canyon Road
City of Industry, CA 91745
Trade Name: Cell Wash/Infusion Bag Set
Cleared Date: 13-JUL-1999
Cleared Under MEDSEP Corp.

BK120026-0  MEDSEP Corporation
1630 Industrial Park Street
Covina, CA 91722
Trade Name: Pall Celeris fPC System
Cleared Date: 29-JUN-2012

BK930021-0  MIGADAS INC
482 Hudson Terrace
Englewood Cliffs, NY 07632
Trade Name: Samplink
Cleared Date: 16-NOV-1993

BK970022-0  MIGADAS INC
482 Hudson Terrace
Englewood Cliffs, NY 07632
Trade Name: samplink
Cleared Date: 18-SEP-1997

BK910007-0  MMED
609 19th Avenue, S.W.
Rochester, MN 55902
Trade Name: MMED Vapor Condensation Blood Warmer
Cleared Date: 16-MAR-1992

BK910004-0  MPI/Dupaco, Inc.
2620 Temple Heights Drive
Oceanside, CA 92056
Trade Name: Dupaco Blood/Fluid Warming Cuff Set
Cleared Date: 21-FEB-1992

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

BK050041-0  MacoProductions S.A.S.
c/o Hoppe Regulatory Consultants
2335 massey Lane
Decatur, GA 30033
Trade Name: Leucolab LCG2 Leukoreduction System for 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 chaussee Fernand Forest,
Tourcoing France 59200
Trade Name: MacoMix HM20 and optional Hemolog 6 Software
Cleared Date: 11-AUG-2017

BK170085-0  MacoProductions S.A.S.
200 chaussee Fernand Forest,
Tourcoing France 59200
Trade Name: MacoPress Smart (MPS) and DMS Plus
Cleared Date: 09-NOV-2017

BK180306-0  MacoProductions S.A.S.
200 chaussee Fernand Forest,
Tourcoing France 59200
Trade Name: MacoPress Smart Smarter and DMS
BK960075-0  Mallinckrodt Medical, Inc.
675 McDonnell Boulevard
St. Louis, MO 63134
Trade Name: Alton Dean Fluid Warmer, FW-537
Cleared Date: 28-FEB-1997

BK090051-0  McKesson Provider Technologies
5995 Windward Parkway
Alpharetta, GA 30005
Trade Name: Horizon MobileCare Transfusion
Cleared Date: 28-MAY-2010

BK180219-0  Medical Information Technology, Inc.
Meditech Circle
Westwood, MA 02090
Trade Name: MEDITECH Expanse Blood Bank
Cleared Date: 12-SEP-2018

BK180031-0  Medical Marketing Consultants
3 Bethesda Metro Center, Suite 750
Bethesda, MD 20814
Trade Name: sHLA-STAT B27 ELISA for HLA-B27 Typing
Cleared Date: 20-AUG-1993

BK140092-0  Medion Grifols Diagnostics AG
Bonnstrasse 9
Duedingen,
Trade Name: DG Gel Extended Control
Cleared Date: 11-APR-2014

BK180280-0  Medion Grifols Diagnostics AG
Bonnstrasse 9
Duedingen,
Trade Name: DG Gel Essential Control
Cleared Date: 17-JAN-2019

BK980034-0  Mediware Information Systems, Inc.
1121 Old Walt Whitman Road
Melville, NY 11747
Trade Name: Hemocare Blood Bank Management System - Revision 5.2
Cleared Date: 10-DEC-1998

BK010052-0  Mediware Information Systems, Inc.
9000 Harry Hines Blvd
Dallas, TX 75235
Trade Name: LifeTrak Lab - 2.03
Cleared Date: 17-JUN-2002

BK020046-0  Mediware Information Systems, Inc.
900 Oakmont Lane
Westmont, IL 60659
Trade Name: Hemocare LifeLine - Version, 1.0
Cleared Date: 14-FEB-2003

BK030078-0  Mediware Information Systems, Inc.
4545 Fuller Drive, Ste 320
Irving, TX 75038
Trade Name: HCLL - 2.6
Cleared Date: 08-APR-2004
Cleared Date: 26-OCT-1992
Cleared Under Pall Bio Medical

BK940018-0 Medsep Corporation
2200 Northern Boulevard
East Hills, NY 11548-1289
Trade Name: Pall AutoprocessorTM System
Cleared Date: 07-SEP-1994
Cleared Under Pall Bio Medical

BK100058-0 Medsep Corporation
1630 INDUSTRIAL PARK
COVINA, CA 91722
Trade Name: The Pall Celeris fPC System
Cleared Date: 24-FEB-2011

BK010032-0 Medserv, Inc.
71 South Bedford Road
Mount Kisco, NY 10549
Trade Name: Plasmapheresis Data System III - 1.0
Cleared Date: 05-FEB-2002

BK030040-0 Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132
Trade Name: Magellan Autologous Platelet Separation System
Cleared Date: 03-SEP-2003

BK040068-0 Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132
Trade Name: Magellan Autologous Platelet Separator System
Cleared Date: 09-NOV-2004

BK940010-0 Mercia Diagnostics Limited
Mercia House, Broadford Park
Shalford, Guildford GU4 8EW, United Kingdom
Trade Name: CAPTIA TM Syphilis-G
Cleared Date: 03-JAN-1995

BK920004-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MGR Model ERB-5-0378
Cleared Date: 12-MAR-1992

BK920013-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Diluent 2
Cleared Date: 29-SEP-1993

BK920014-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Centrifuge
Cleared Date: 29-SEP-1993

BK920016-0 Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Buffered Gel Card
Cleared Date: 29-SEP-1993

BK920030-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Diluent 1
Cleared Date: 29-SEP-1993

BK930030-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Diluent 2 Plus
Cleared Date: 12-JAN-1994

BK940034-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Control Card
Cleared Date: 27-JUL-1994

BK950025-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Incubator
Cleared Date: 08-MAY-1995

BK950026-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: MTS Work Table
Cleared Date: 15-MAY-1995

BK950027-0  Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
Trade Name: ID-Pipetor
Cleared Date: 01-JUN-1995

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

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

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

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

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

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

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

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

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

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

BK160061-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS™ 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

BK840023-0 Microdrop, Incorporation  
2227 Corinth Ave.  
Los Angeles, CA 90064  
Trade Name: Leukocyte Typing Serum Trays  
Cleared Date: 12-OCT-1984

BK840013-0 Microdrop, Incorporation  
2227 Corinth Ave.  
Los Angeles, CA 90064  
Trade Name: Lambda Cell Tray  
Cleared Date: 20-NOV-1984

BK100008-0 Micronics  
8463 154th Avenue NE  
Redmond, WA 98052  
Trade Name: ABORhCard
Cleared Date: 30-APR-2010

BK910034-0  Microwave Medical System
310-312 School St.
Acton, MA 01720
Trade Name: QWIK-1 Bld. and Plasma Warmer
Cleared Date: 29-JUL-1993

BK940003-0  Microwave Medical System
310-312 School St.
Acton, MA 01720
Trade Name: Qwik - 1 TM - 500
Cleared Date: 24-FEB-1994

BK970044-0  Microwave Medical System
310-312 School St.
Acton, MA 01720
Trade Name: ThermoStat 900
Cleared Date: 23-JAN-1998

BK970045-0  Microwave Medical System
310-312 School St.
Acton, MA 01720
Trade Name: ThermoStat 900 Blood & IV Fluid Adm. Set
Cleared Date: 06-MAR-1998

BK860016-0  Miles, Inc.
4th and Parker Streets, P.O. Box 1986
Berkeley, CA 94701-1986
Trade Name: PENTEX MOD-U-CYTE II & VIII
Cleared Date: 17-APR-1987

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

BK030065-0  Mississippi Blood Services, Inc.
1995 Lakeland Drive
Jackson, MS 39216
Trade Name: WebLab Online Laboratory System - 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: Compo cool
Cleared Date: 27-SEP-1995

BK960084-0  NPBI
Runde ZZ 41, 7881 HM Emmer Compascuum
Emmer-Compascuum, Netherlands
Trade Name: Gambro Hemofreeze Bag
Cleared Date: 28-MAY-1998

BK940053-0  Nanoentek, Inc.
300 Washington St., STE 416
Newton, MA 02458
Trade Name: Olympus PK System
Cleared Date: 29-NOV-1995
Cleared Under Schiff & Company

BK120015-0  Nanoentek, Inc.
300 Washington St., STE 416
Newton, MA 02458
Trade Name: ADAM-rWBC
Cleared Date: 24-JUL-2012

BK120068-0  Nanoentek, Inc.
300 Washington St., STE 416
Newton, MA 02458
Trade Name: ADAM-rWBC
Cleared Date: 05-DEC-2012
Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name: NSBF211 (Nor-Lake Scientific Freezers, 21 ft 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, 48 ft 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, 6 ft 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: PROCLEX® 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
Hasseltigen 1
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® 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
One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: LabType Visual
Cleared Date: 09-AUG-2004

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

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

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

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

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

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

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

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

One Lambda, Inc.
21001 Kittrridge 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 OrSense Ltd
17 Ha'Mefalsim St
Petah Tikva, Kiryat Arie Israel 4951447
Trade Name: NBM-200 Pulse Oximeter and Hemoglobin Monitor
Cleared Date: 09-MAY-2019

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

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

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

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

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

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

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

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

BK920034-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: Ortho BioVue System
Cleared Date: 09-MAY-1995
| BK96003-0 | Ortho-Clinical Diagnostics, Inc.  
| 1001 U.S. Highway 202  
| Raritan, NJ 08869-0606  
| Trade Name: Ortho Summit System  
| Cleared Date: 19-OCT-1998 |
| BK960052-0 | Ortho-Clinical Diagnostics, Inc.  
| 1001 U.S. Highway 202  
| Raritan, NJ 08869-0606  
| Trade Name: Ortho Summit Processor  
| Cleared Date: 19-OCT-1998 |
| BK990030-0 | Ortho-Clinical Diagnostics, Inc.  
| 1001 U.S. Highway 202  
| Raritan, NJ 08869-0606  
| Trade Name: Ortho Lab with Ortho Lab IC (Instrument Concentrator)  
| Cleared Date: 03-APR-2000 |
| BK050044-0 | Ortho-Clinical Diagnostics, Inc.  
| 1001 U.S. Highway 202  
| Raritan, NJ 08869-0606  
| Trade Name: Genetic Systems HIV-1/HIV-2 PLUS Ortho Assay Protocol Disk  
| Cleared Date: 03-NOV-2006 |
| BK050046-0 | Ortho-Clinical Diagnostics, Inc.  
| 1001 U.S. Highway 202  
| Raritan, NJ 08869-0606  
| Trade Name: Genetic Systems HBsAg ELA 3.0 Ortho Assay Protocol Disk  
| Cleared Date: 13-JAN-2006 |
| BK070028-0 | Ortho-Clinical Diagnostics, Inc.  
| 100 Indigo Creek Drive  
| Rochester, NY 14626-5101  
| Trade Name: VITROS Immunodiagnostic Products Anti-HIV 1+2 Controls  
| Cleared Date: 10-APR-2008 |
| BK090074-0 | Ortho-Clinical Diagnostics, Inc.  
| 1001 U.S. Highway 202  
| Raritan, NJ 08869-0606  
| Trade Name: Ortho Summit System  
| Cleared Date: 27-MAY-2009 |
| BK100040-0 | Ortho-Clinical Diagnostics, Inc.  
| 100 Indigo Creek Drive  
| Rochester, NY 14626-5101  
| Trade Name: VITROS Immunodiagnostic Products Anti-HIV 1+2 Controls  
| Cleared Date: 22-JUL-2010 |
| BK100061-0 | Ortho-Clinical Diagnostics, Inc.  
| 1001 U.S. Highway 202  
| Raritan, NJ 08869-0606  
| Trade Name: ORTHO VERSEIA Pipetter as part of the ORTHO Summit System  
| Cleared Date: 28-OCT-2010 |
| BK110026-0 | Ortho-Clinical Diagnostics, Inc.  
| 1001 U.S. Highway 202  
| Raritan, NJ 08869-0606  
| Trade Name: Ortho Summit System (OSS)  
| Cleared Date: 28-JUN-2011 |
BK120006-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO VERSEIA Pipetter as Part of the ORTHO Summit System (OSS) v 3.0
Cleared Date: 15-MAR-2012

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

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

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

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

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

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
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 Tecnologico de Bizkaia  
Derio, Bizkaia.  
Trade Name: ID CORE CONTROL  
Cleared Date: 11-OCT-2018

BK010017-0 Psyche Systems Corp  
Ten Laurel Avenue  
Wellesley, MA 02481  
Trade Name: System Blood Bank (SBB) Software - 3.0  
Cleared Date: 04-SEP-2001

BK180188-0 PuriBlood Medical Co. Ltd.  
2F., No.11, Gongye E. 9th Rd.  
Paoshan Hsiang  
Hsinchu Hsien Taiwan 30075  
Trade Name: Leukocyte Reduction Filter for Red Blood Cells  
Leukocyte reduction filter for red blood cells  
Cleared Date: 23-NOV-2018

BK840020-0 Queue Systems  
22 Airport Industrial Park Rd., Box 1901  
Parkersburg, WV 26102  
Trade Name: Cryostar  
Cleared Date: 23-OCT-1984

BK990005-0 R & D Systems, Inc  
614 McKinley Place N.E.  
Minneapolis, MN 55413  
Trade Name: StatusFlow Pro  
Cleared Date: 21-JUN-1999

BK000035-0 R & D Systems, Inc  
614 McKinley Place N.E.  
Minneapolis, MN 55413  
Trade Name: R & D Leuko-Reduced RBC Control  
Cleared Date: 13-DEC-2000

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

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

BK040063-0 R & D Systems, Inc  
614 McKinley Place N.E.  
Minneapolis, MN 55413  
Trade Name: R & D Plasma Hemoglobin Hematology Control  
Cleared Date: 17-SEP-2004

BK910012-0 ROCHE BIOMEDICAL LABORATORIES, INC.
112 ORANGE DRIVE
ELON COLLEGE, NC 27244
Trade Name: HLA CLASS I PHENOTYPING TRAYS
Cleared Date: 06-JAN-1992

BK860034-0  Reagent Laboratory, Inc.
300 East Ottawa Avenue
Louisville, KY 40209
Trade Name: Sodium Chloride 1.3%
Cleared Date: 01-JUN-1987

BK140211-0  Reapplix Aps
Blokken 45
Birkerod, Denmark
Trade Name: 3C Patch System
Cleared Date: 24-FEB-2016

BK170002-0  Reapplix Aps
Blokken 45
Birkerod, Denmark
Trade Name: 3C Patch System
Cleared Date: 04-APR-2017

BK170095-0  RedDress Ltd
Shkedim Street 11
Pardes Hanna, Israel 370110
Trade Name: RD1 System
Cleared Date: 14-JUN-2018

BK090048-0  RegenLab SA
3428 Avenue Marcil
Montreal, Quebec Canada H4A 2Z3
Trade Name: RegenKit-THT
Cleared Date: 18-MAY-2010
Cleared Under RegenLab SARL

BK110061-0  RegenLab SA
En Budron B2
CH-1052 Le Mont sur Lausanne,
Switzerland
Trade Name: RegenKit-BCT Family Kits
Cleared Date: 08-MAY-2012
Cleared Under RegenLab SARL

BK120057-0  RegenLab SA
3428 Avenue Marcil
Montreal, Quebec Canada H4A 2Z3
Trade Name: A-CP-Kit Family Kits
Cleared Date: 08-AUG-2013

BK120066-0  RegenLab SA
3428 Avenue Marcil
Montreal, Quebec Canada H4A 2Z3
Trade Name: RegenKit-ATS-3
RegenKit-BCT-1 Plus
RegenKit-BCT-2 Plus
Cleared Date: 05-FEB-2014

BK170128-0  Reichert Inc.
3362 Walden Ave
Suite 100
Depew, NY 14043
Trade Name: TS Meter-DSP
Cleared Date: 19-DEC-2017
BK880029-0  Revco/Lindberg
            275 Aiken Road
            Asheville, NC 28804
            Trade Name: MBF700 Blood Freezer
            Cleared Date: 16-JUN-1989

BK890023-0  Revco/Lindberg
            275 Aiken Road
            Asheville, NC 28804
            Trade Name: HLT-20DR-87 Blood Freezer
            Cleared Date: 21-SEP-1990

BK890025-0  Revco/Lindberg
            275 Aiken Road
            Asheville, NC 28804
            Trade Name: HLT-50V-4BB Blood Refrigerator
            Cleared Date: 02-FEB-1990

BK890026-0  Revco/Lindberg
            275 Aiken Road
            Asheville, NC 28804
            Trade Name: REB3704 Blood Refrigerator
            Cleared Date: 02-FEB-1990

BK950054-0  Revco/Lindberg
            275 Aiken Road
            Asheville, NC 28804
            Trade Name: Blood Storage Refrigerator REB2304
            Cleared Date: 11-JAN-1996

BK950066-0  Revco/Lindberg
            275 Aiken Road
            Asheville, NC 28804
            Trade Name: Revco HLT 30V-4BB
            Cleared Date: 31-JAN-1996

BK890006-0  Rexco
            275 Aiken Road
            Asheville, NC 28804
            Trade Name: MBF 500 Blood Freezer
            Cleared Date: 16-JUN-1989

BK020018-0  Roche Molecular Systems, Inc.
            4300 Hacienda Drive
            P.O. Box 9002
            Pleasanton, CA 94588-0900
            Trade Name: Cobas AmpliScreen System
            Cleared Date: 26-NOV-2002

BK020025-0  Roche Molecular Systems, Inc.
            4300 Hacienda Drive
            P.O. Box 9002
            Pleasanton, CA 94588-0900
            Trade Name: COBAS AmpliScreen Data Output Management System (DOMS) - 1.00.04
            Cleared Date: 10-DEC-2002

BK140195-0  Roche Molecular Systems, Inc.
            4300 Hacienda Drive
            P.O. Box 9002
            Pleasanton, CA 94588-0900
            Trade Name: Cobas p 680 Instrument Cobas® 8800 System
            Cleared Date: 20-OCT-2016
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: Aldecount Progenitor Cell Enumeration Kit  
Cleared Date: 02-DEC-2005

BK130052-0  STRATEC Biomedical UK Limited  
1 Barberry Court, Callister Way  
Burton upon Trent  
Trade Name: Procleix NAT Manager Software (Version 1.1)  
Cleared Date: 17-APR-2014

BK160071-0  STRATEC Biomedical UK Limited  
Third Ave, Centrum 100  
Burton upon Trent
Straffordshire, DE14 2WD United Kingdom
Trade Name: Aurora Enterprise - Cat. No. AUR-ENT-001
Cleared Date: 30-OCT-2017

BK160113-0 STRATEC Biomedical UK Limited
98 Main Street
Suite 205
Southington, CT 06489
Trade Name: cobas Synergy Software (Version 1.0)
Cleared Date: 19-APR-2017

BK160124-0 STRATEC Biomedical UK Limited
Third Ave, Centrum 100
Burton upon Trent
Straffordshire, DE14 2WD United Kingdom
Trade Name: ORTHO CONNECT
Cleared Date: 17-OCT-2017

BK160125-0 STRATEC Biomedical UK Limited
Third Ave, Centrum 100
Burton upon Trent
Straffordshire, DE14 2WD United Kingdom
Trade Name: Procleix? NAT Manager? v1.2
Software - v1.2
Cleared Date: 25-APR-2017

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
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
UltraCrit™ 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.
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 27-MAR-2012
Cleared Under Siemens Healthcare Diagnostics Inc.

Trade Name: ADVIA Centaur System (Software Version 4.0 with SP4)
Cleared Date: 08-JUN-2015

Trade Name: ADVIA Centaur XP System (SW v 7.1)
Cleared Date: 08-JUN-2015

Trade Name: PPIS - Version 2.0
Cleared Date: 07-AUG-1998
Cleared Under Bayer Corporation

Trade Name: Plasma Procurement Information System (PPIS) - 3.0
Cleared Date: 03-NOV-1999
Cleared Under Bayer Corporation

Trade Name: Plasma Procurement Information System (PPIS) - Version 4.0
Cleared Date: 17-NOV-1999
Cleared Under Bayer Corporation

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

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

Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 20-OCT-2008
<table>
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<tr>
<th>Identifier</th>
<th>Company Name</th>
<th>Address</th>
<th>Trade Name</th>
<th>Cleared Date</th>
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<tbody>
<tr>
<td>BK080073-0</td>
<td>Siemens Medical Solutions Diagnostics</td>
<td>P.O. Box 2466 Berkeley, CA 94702-0466</td>
<td>TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System</td>
<td>15-JAN-2009</td>
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<td>BK060004-0</td>
<td>Smith &amp; Nephew</td>
<td>1450 Brooks Road Memphis, TN 38116</td>
<td>Promote Platelet Rich Concentrate (PRC) Preparation System</td>
<td>02-MAY-2006</td>
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<td>BK850011-0</td>
<td>Smithkline Beckman Corp.</td>
<td>999 West Valley Road Wayne, PA 19087</td>
<td>Accugenics (Tray)</td>
<td>07-AUG-1985</td>
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<tr>
<td>BK850012-0</td>
<td>Smithkline Beckman Corp.</td>
<td>999 West Valley Road Wayne, PA 19087</td>
<td>Accugenics (HLA Control Cells)</td>
<td>07-AUG-1985</td>
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<td>BK080047-0</td>
<td>SofTov Ltd</td>
<td>32 HaShacham Street Petach Tikva, Israel 49170</td>
<td>AutoFusion - v3.02</td>
<td>05-JUN-2009</td>
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<tr>
<td>BK040028-0</td>
<td>Soft Computer Consultants Inc.</td>
<td>34350 U.S. HWY 19 N. Palm Harbor, FL 34684</td>
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</tbody>
</table>
Trade Name: SoftBank II with SoftScape - 23
Cleared Date: 07-MAY-2004

BK040048-0 Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name: SoftBank II with Database Management System Interface (DMSI) v23.1
Cleared Date: 23-AUG-2004

BK970032-0 Sorvall, Inc.
31 Pecks Lane
Newtown, CT 06470
Trade Name: RC12BP
Cleared Date: 05-DEC-1997

BK030064-0 Stemco Biomedical, Incorporated
2810 Meridian Parkway Suite 148
Durham, NC 27713
Trade Name: Aldecount Progenitor Cell Enumeration Kit
Cleared Date: 31-DEC-2003

BK040075-0 Stemco Biomedical, Incorporated
2810 Meridian Parkway Suite 148
Durham, NC 27713
Trade Name: Aldecount Progenitor Cell Enumeration Kit
Cleared Date: 06-JAN-2005

BK860030-0 Stephens Scientific
7 Astro Place Box 1116
Denville, NJ 07834
Trade Name: Stephens Scientific Certified Blood Bank Saline
Cleared Date: 16-DEC-1986

BK870015-0 Stephens Scientific
7 Astro Place Box 1116
Denville, NJ 07834
Trade Name: Certified Blood Bank Saline, 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 Steriicon Inc.
2315 Gardner Road.
Broadview, IL 60153
Trade Name: RCM-10 Pediatric Sized Freezing Bag
Cleared Date: 09-NOV-1988

BK920022-0 Steriicon Inc.
2315 Gardner Road.
Broadview, IL 60153
Trade Name: MB-30 Empty Plastic Containers
Cleared Date: 03-JUN-1993
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
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-DRB Typing Kit for use with Luminex
Cleared Date: 13-NOV-2008

BK090018-0  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: 04-JUN-2009

BK010006-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: LIFECODES Evolution Software, version 1.0
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 Component 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 Component Collection System
Cleared Date: 18-SEP-2002
Cleared Under Gambro BCT, Inc

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK160082-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: T-Cuff
Cleared Date: 19-AUG-2016

BK160108-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: TSCD-II Sterile Tubing Welder with or without Trucise Total System (TM), Model ME-SC203A
Cleared Date: 23-NOV-2016

BK170059-0  Terumo BCT, Inc
BK170098-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: Trima Accel (R) Blood Collection System
Cleared Date: 07-JUL-2017

BK170157-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: TSCD-II Sterile Tubing Welder with or without Trucise Total System (TM)
Cleared Date: 29-SEP-2017

BK180231-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: Trima Accel (R) Blood Collection System
Cleared Date: 06-APR-2018

BK180258-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: Vista Information System
Cleared Date: 17-AUG-2018

BK190332-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: Trima Accel Blood Collection System
Cleared Date: 18-JAN-2019

BK820015-0  Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name: Plasmaflex Pooling Bottle
Cleared Date: 16-MAY-1990

BK850017-0  Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name: Imugard Leukocyte Filter
Cleared Date: 17-AUG-2018

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: Immugard III-PL
Cleared Date: 28-SEP-2001
BK020033-0  Terumo Medical Corporation 125 Blue Ball Road Elkton, MD 21921 Trade Name: Imugard III-PL Leukocyte reduction filter Cleared Date: 22-MAY-2003

BK040082-0  Terumo Medical Corporation 125 Blue Ball Road Elkton, MD 21921 Trade Name: TSCD-II Terumo Sterile Tubing Welder Cleared Date: 05-APR-2005

BK070018-0  Terumo Medical Corporation 125 Blue Ball Road Elkton, MD 21921 Trade Name: TRUCISE Total System Cleared Date: 22-JAN-2008

BK110071-0  Terumo Medical Corporation 950 Elkton Blvd Elkton, MD 21921 Trade Name: TSCD (R) II Sterile Tubing Welder & Trucise Total System (R) Cleared Date: 12-SEP-2012

BK980002-0  Teva Medical LTD 482 Hudson Terrace Englewood Cliffs, NJ 07632 Trade Name: SegMed Cleared Date: 02-MAR-1998

BK060060-0  Texas BioGene, Inc. 635 Presidential Drive Richardson, TX 75081 Trade Name: Morgan HLA SSP ABDR Typing Kit Cleared Date: 22-MAR-2007

BK080039-0  Texas BioGene, Inc. 635 Presidential Drive Richardson, TX 75081 Trade Name: Morgan HLA SSP ABCDRDQ Typing Kit Cleared Date: 22-APR-2009

BK050058-0  The Surgical Company International Terminalweg 19a Amersfoort, Netherlands 3821 AJ Trade Name: Fluido Blood and Fluid Warmer System Cleared Date: 05-MAY-2006

BK070055-0  The Surgical Company International Terminalweg 19a Amersfoort, Netherlands 3821 AJ Trade Name: Fluido Air Guard Fluido Compressor Fluido IV-Pole Fluido Pressure Chamber Cleared Date: 15-JAN-2008

BK950067-0  Thermal Transfer Technology 681 Main Street Placerville, CA 95667
Trade Name: Thermal Ware
Cleared Date: 14-FEB-1996

BK160044-0 THERMO ELECTRON LED GMBH (A SUBSIDIARY OF THERMO FISHER SCIENTIFIC INC.)

Am Kalkberg
Osterode am Harz.

Trade Name: Thermo Scientific CW3 Cell Washer
Cleared Date: 07-OCT-2016

BK180198-0 THERMOGENESIS CORP
2700 Citrus Rd
Rancho Cordova, CA 75741

Trade Name: AXP II AutoXpress Platform
Cleared Date: 14-NOV-2018

BK960072-0 THERMOGENESIS
3146 Gold Camp Drive
Suite 206
Rancho Cordova, CA 95670-6022

Trade Name: CryoSeal System
Cleared Date: 12-FEB-1999

BK960074-0 THERMOGENESIS
3146 Gold Camp Drive
Suite 206
Rancho Cordova, CA 95670-6022

Trade Name: HemoMatic Blood Collection Monitor
Cleared Date: 03-APR-1997

BK030011-0 THERMOGENESIS
3146 Gold Camp Drive
Suite 206
Rancho Cordova, CA 95670-6022

Trade Name: ThermoGenesis Thawer
Cleared Date: 10-JUN-2003

BK070006-0 THERMOGENESIS
2711 Citrus Road
Rancho Cordova, CA 95742

Trade Name: AXP AutoXpress Platform
Cleared Date: 05-OCT-2007

BK100066-0 THERMOGENESIS
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
Trade Name: Timestrip® Blood Temp 10 (BT10)
Cleared Date: 14-DEC-2015

Trade Name: Timestrip Blood Temp 10
Cleared Date: 22-JUL-2019

Trade Name: Trayser DR/DQ Typing Tray Kit
Cleared Date: 25-APR-1985

Trade Name: Kendall LIFETRACE Umbilical Blood Collection Kit
Cleared Date: 03-NOV-2003

Trade Name: TypeSafe Segment Dispenser
Cleared Date: 05-OCT-2007

Trade Name: Typesafe 2.0 Segment Piercing Device (Model Number SP0201QD & SP0201QM)
Cleared Date: 28-DEC-2015

Trade Name: HLA Typing Tray
Cleared Date: 04-MAR-1983

Trade Name: Umbilicup
Cleared Date: 28-JAN-1998

Trade Name: Umbilicup II Cord Blood System
Cleared Date: 06-JAN-1998

Trade Name: Atago SP-D2 Refractometer
Cleared Date: 02-JAN-2002
Val Tech Diagnostics
14 Werner Camp Road
Pittsburgh, PA 15238
Trade Name: Normal Saline-Buffered
Cleared Date: 31-JUL-1987

Val Tech Diagnostics
14 Werner Camp Road
Pittsburgh, PA 15238
Trade Name: Buffered Normal Saline Concentrate
Cleared Date: 11-APR-1988

Verax Biomedical Incorporated
148 Bartlett Street
Marlborough, MA 01752
Trade Name: Platelet PGD Controls
Platelet PGD Test
Cleared Date: 17-SEP-2007

Verax Biomedical Incorporated
148 Bartlett Street
Marlborough, MA 01752
Trade Name: Platelet PGD Test System
Cleared Date: 10-NOV-2009

Verax Biomedical Incorporated
148 Bartlett Street
Marlborough, MA 01752
Trade Name: Platelet PGD Test System
Cleared Date: 08-SEP-2011

Verax Biomedical Incorporated
148 Bartlett Street
Marlborough, MA 01752
Trade Name: Platelet PGD(R) Test System
Cleared Date: 13-MAY-2015

Verax Biomedical Incorporated
148 Bartlett Street
Marlborough, MA 01752
Trade Name: Platelet PGD Test System
Cleared Date: 06-APR-2017

Vertical Spine, LLC
2201 Marconi Road
Wall, NJ 07719
Trade Name: FIBRINET (R) Autologous PRP System
Cleared Date: 01-AUG-2012
Cleared Under Cascade Medical Enterprises, LLC

Visible Genetics, Inc.
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 Canada
Trade Name: Trugene HIV-1 Genotyping Kit and
Open Gene DNA Sequencing System
Cleared Date: 24-APR-2002

Visible Genetics, Inc.
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 Canada
Trade Name: TRUGENE HIV-1 Genotyping Kit and
OpenGene DNA Sequencing System
Cleared Date: 07-NOV-2002

Visible Genetics, Inc.
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 Canada
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 14-MAR-2003

BK910010-0  WHITTAKER BIOPRODUCTS, INC.
8830 Biggs Ford Road
Walkersville, MD 21793
Trade Name: ENDOTOXIN CHALLENGE VIALS
Cleared Date: 09-AUG-1991

BK860039-0  Wako Chemicals USA, Inc.
12300 Ford Road, Suite 130
Dallas, TX 75234
Trade Name: Toxinometer ET-201
Cleared Date: 10-FEB-1987

BK910005-0  Whitman Medical Corporation
990 Raritan Road
Clark, NJ 07066
Trade Name: Safe-T-Vue Irreversible Temperature Indicator
Cleared Date: 12-MAY-1992

BK950059-0  Wyndgate Technologies
11121 Sun Center Drive
Suite C
Rancho Cordova, CA 95670
Trade Name: SafeTrace
Cleared Date: 14-APR-1997

BK980023-0  Wyndgate Technologies
11060 White Rock Road
Suite 200
Rancho Cordova, CA 95670
Trade Name: SafeTrace TX, version 1.0
Cleared Date: 29-JAN-1999

BK070010-0  Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: El Dorado 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 ElDorado Donor
Cleared Date: 20- NOV-2009

BK100002-0 Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: Component Manufacturing Interface for ElDorado Donor
Cleared Date: 24- FEB-2010

BK860005-0 bioMerieux, Inc.
5300 S. Portland Avenue
Oklahoma City, OK 73119
Trade Name: Plasma Collection Bag
Cleared Date: 19-DEC-1986
Cleared Under BioMerieux, Inc.

BK870019-0 bioMerieux, Inc.
5300 S. Portland Avenue
Oklahoma City, OK 73119
Trade Name: Quik-Chek
Cleared Date: 19- MAY-1988
Cleared Under BioMerieux, Inc.

BK880003-0 bioMerieux, Inc.
5300 S. Portland Avenue
Oklahoma City, OK 73119
Trade Name: Therapeutic Plasmapheresis Collection Bag
Cleared Date: 11- MAR-1988
Cleared Under BioMerieux, Inc.

BK920037-0 bioMerieux, Inc.
5300 S. Portland Avenue
Oklahoma City, OK 73119
Trade Name: PEG+
Cleared Date: 21- OCT-1993
Cleared Under BioMerieux, Inc.

BK960026-0 bioMerieux, Inc.
100 Akzo Avenue
Durham, NC 27712
Trade Name: Status Symbol TM II System Software
Cleared Date: 16- MAR-1999
Cleared Under Organon Teknika Corporation

BK000042-0 bioMerieux, Inc.
100 Akzo Avenue
Durham, NC 27712
Trade Name: BacT/ALERT Culture Bottles
Cleared Date: 15- FEB-2002
Cleared Under BioMerieux, Inc.

BK020022-0 bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
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bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
BacT/ALERT® BPN Culture Bottle
Cleared Date: 01-FEB-2018

BK180266-0  bioMérieux, 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