Currently Cleared CBER 510(k) Clearances
As of May 05, 2015
Sorted by Applicant Name

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

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

BK100005-0  ALBA Bioscience Limited (doing business as Quotient)
21 Ellen’s Glen Road
Liberton, Edinburgh
EH17 7QT
Scotland, UNITED KINGDOM, United Kingdom
Trade Name: ALBAcyte IgG Sensitize 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
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
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
Trade Name: ALBAsure® QC Kit
Cleared Date: 01-APR-2015

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

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

BK970042-0  Abbott Laboratories  
100 Abbott Park Road  
Abbott Park, IL 60064-3500  
Trade Name: ABBOTT PRISM System  
Cleared Date: 14-JUN-1999

BK010036-0  Abbott Laboratories  
100 Abbott Park Road  
Abbott Park, IL 60064-3500  
Trade Name: ABBOTT PRISM Retest Server - 1.0  
Cleared Date: 17-JUL-2002

BK060028-0  Abbott Laboratories  
100 Abbott Park Road  
Abbott Park, IL 60064-3500  
Trade Name: Abbott PRISM Retest Server  
Cleared Date: 07-JUN-2006

BK080015-0  Abbott Laboratories  
100 Abbott Park Road  
Abbott Park, IL 60064-3500  
Trade Name: ABBOTT PRISM Director V2.0  
Cleared Date: 24-APR-2008

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

BK810599-0  Accugenics, Inc.  
Costa Mesa, CA 92626  
Trade Name: Dade Rh Control Reagent  
Cleared Date: 31-MAR-1981
BK820004-0  Accugenics, Inc.
Costa Mesa, CA 92626
Trade Name: Trans-Type Reagents
Cleared Date: 29-OCT-1982

BK830001-0  Accugenics, Inc.
Costa Mesa, CA 92626
Trade Name: Polycation Potentiator System
Cleared Date: 06-MAY-1983

BK860038-0  Accugenics, Inc.
Costa Mesa, CA 92626
Trade Name: Data-Fi Thrombin Reagent
Cleared Date: 16-JAN-1987

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK860002-0  Amtec Diagnostics International Inc.
            1107 IH-45 South
            Conroe, TX 77305
Trade Name: Bovine Albumin 22%
Cleared Date: 03-MAR-1986

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK930027-0  BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name: Accurun 1
Cleared Date: 25-OCT-1994
Cleared Under Boston Biomedica, Inc.
BK970004-0  BBI Diagnostics, A SeraCare Company  
375 West Street  
West Bridgewater, MA 02379  
Trade Name: ACCURUN155  
Cleared Date: 23-APR-1999  
Cleared Under Boston Biomedica, Inc.

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

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

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

BK040016-0  BBI Diagnostics, A SeraCare Company  
375 West Street  
West Bridgewater, MA 02379  
Trade Name: ACCURUN 305 HCV RNA Positive Quality Control  
Cleared Date: 17-DEC-2004  
Cleared Under Boston Biomedica, Inc.

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

BK040067-0  BBI Diagnostics, A SeraCare Company  
375 West Street  
West Bridgewater, MA 02379  
Trade Name: ACCURUN 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV)  
Cleared Date: 19-NOV-2004  
Cleared Under Boston Biomedica, Inc.
BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name: ACCURUN 365 West Nile Virus RNA Positive Quality Control
Cleared Date: 12-JUN-2006

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

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

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

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

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

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

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

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

BK100063-0  Barkey GmbH & Co KG
Gewerbestrasse 8
D-33818 Leopoldshohe
Leopoldshohe Germany 33818
Trade Name: plasmatherm
Cleared Date: 17-NOV-2011

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

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

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

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

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

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

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

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

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

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

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

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

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

BK9700017-0  BioMerieux  
1022 Hingham Street  
Rockland, MA 02370  
Trade Name: HLA-DR Oligo Detection Kit  
Cleared Date: 28-MAY-1998

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

BK8700019-0  BioMerieux, Inc.  
5300 S. Portland Avenue  
Oklahoma City, OK 73119  
Trade Name: Quik-Chek  
Cleared Date: 19-MAY-1988

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

BK9200037-0  BioMerieux, Inc.  
5300 S. Portland Avenue  
Oklahoma City, OK 73119  
Trade Name: PEG+  
Cleared Date: 21-OCT-1993

BK9600026-0  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

BK0000042-0  BioMerieux, Inc.  
100 Akzo Avenue  
Durham, NC 27712  
Trade Name: BacT/ALERT Culture Bottles  
Cleared Date: 15-FEB-2002

BK0200022-0  BioMerieux, Inc.  
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT SN Culture Bottle
Cleared Date: 10-OCT-2002

BK020023-0 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT SA Culture Bottle
Cleared Date: 10-OCT-2002

BK020060-0 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: NuclieSens HIV-1 QT RNA External Controls
Cleared Date: 18-DEC-2002

BK030034-0 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPN Culture Bottle
Cleared Date: 18-JUL-2003

BK030035-0 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPA Culture Bottle
Cleared Date: 06-AUG-2003

BK030075-0 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPN Culture Bottles
Cleared Date: 08-MAR-2004

BK030076-0 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPA Culture Bottles
Cleared Date: 08-MAR-2004

BK050037-0 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPA Culture Bottle
Cleared Date: 27-DEC-2005

BK050043-0 BioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPN Culture Bottle
Cleared Date: 27-DEC-2005

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

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
Plasmmax Plasma Concentrator with GPS Mini Platelet Concentrate Separation Kit with ACD-A
Cleared Date: 22-FEB-2007
Cleared Under Biomet, Inc.

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

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

BK080004-0  Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name: Clotalyst and GPS III Mini Platelet Concentrate Separation Kit with ACD-A
Clotalyst and GPS III Platelet Concentrate Separation Kit with ACD-A
Cleared Date: 19-DEC-2008

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

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

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

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

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

BK970018-0  Biometric Imaging, Inc.
1025 Terra Bella Avenue
Mountain View, CA 94043
Trade Name: STELLer CD34 Assay
Cleared Date: 18-AUG-1998
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<tr>
<th>Block Number</th>
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<th>Address</th>
<th>Trade Name</th>
<th>Cleared Date</th>
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<tr>
<td>BK980035-0</td>
<td>Biopool International, Inc.</td>
<td>1230 Wilson Drive</td>
<td>SliDe Chek</td>
<td>11-JUN-1999</td>
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<tr>
<td>BK060036-0</td>
<td>Biosafe SA</td>
<td>Route du Petit-Eysins</td>
<td>Sepax Cell Separation System and Single Use Kits</td>
<td>03-JAN-2007</td>
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<td>BK090037-0</td>
<td>Biosafe SA</td>
<td>Route du Petit-Eysins</td>
<td>CryoSC Freezing Bag</td>
<td>22-MAR-2010</td>
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<td>BK110022-0</td>
<td>Biosafe SA</td>
<td>Route du Petit-Eysins</td>
<td>Sepax Cell Separation and single use kits</td>
<td>28-OCT-2011</td>
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<tr>
<td>BK840028-0</td>
<td>Biotech Research Laboratories, Inc.</td>
<td>1600 East Gude Drive</td>
<td>Run Control for HBsAg Assay</td>
<td>25-JAN-1985</td>
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<tr>
<td>BK090069-0</td>
<td>Biotechnology Institute, SL.</td>
<td>C/Leonardo Da Vinci 14B, 1B.</td>
<td>Endoret Kit</td>
<td>01-FEB-2010</td>
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<td>01510 Minano (Alava)</td>
<td>Secondary Product Code: FMI, GKT</td>
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<td></td>
<td>D-63266 Dreiech, Germany</td>
<td>Service Pack 4</td>
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</table>
BK950015-0  Biotest Diagnostics Corporation
66 Ford Road, Suite 131
Denville, NJ 07834
Trade Name: Biotest DRB-SSO Typing Kit
Cleared Date: 09-JUN-1995

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

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

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

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

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

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

BK080012-0  Biotest Medical Diagnostics GmbH
P.O. Box 10 21 50
63267 Dreiech, Germany
Trade Name: (1) Seraclone Control ABO+Rh
(2) Coombscell-E
(3) MLB2
Cleared Date: 23-JUL-2008
BK080013-0  Biotest Medical Diagnostics GmbH  
P.O. Box 10 21 50  
63267 Dreiech, Germany  
Trade Name: Alsevers Solution (510(k) exempt but part of system)  
Solidscreen II Control B  
Solidscreen Negative Control  
Tango Optimo Automated Blood Bank Analyzer System with version 3.1  
Cleared Date: 23-JUL-2008

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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: 28-OCT-1998  
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
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<th>Clearance Number</th>
<th>Company Name</th>
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<tr>
<td>BK990040-0</td>
<td>COBE Cardiovascular, Inc.</td>
<td>1201 Oak Street, Lakewood, CO 80215</td>
<td>COBE Trima with the r/LS RBC Leukoreduction Filter</td>
<td>03-MAR-2000</td>
<td>COBE Cardiovascular, Inc.</td>
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<td>BK050033-0</td>
<td>COBE Cardiovascular, Inc.</td>
<td>14401 West 65th Way, Arvada, CO 80004-3599</td>
<td>COBE Angel Whole Blood Separation System</td>
<td>22-AUG-2005</td>
<td>COBE Cardiovascular, Inc.</td>
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<tr>
<td>BK060010-0</td>
<td>COBE Cardiovascular, Inc.</td>
<td>14401 West 65th Way, Arvada, CO 80004-3599</td>
<td>COBE Angel Whole Blood Separation System</td>
<td>27-FEB-2006</td>
<td>COBE Cardiovascular, Inc.</td>
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<td>BK130003-0</td>
<td>CPSI</td>
<td>6600 Wall Street, Mobile, AL 36695</td>
<td>Blood Administration - Version 1800</td>
<td>30-APR-2014</td>
<td>CPSI</td>
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<td>BK020020-0</td>
<td>CSL Behring AG</td>
<td>Wankdorfstrasse 10, 3014 Bern, Switzerland</td>
<td>System for Plasma Identification (SPI) - 1.0</td>
<td>30-OCT-2002</td>
<td>CSL Behring AG</td>
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<td>BK050078-0</td>
<td>CSL Behring AG</td>
<td>Wankdorfstrasse 10, 3014 Bern, Switzerland</td>
<td>System for Plasma Identification (SPI) - 2.0.0</td>
<td>22-DEC-2005</td>
<td>CSL Behring AG</td>
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<td>BK110023-0</td>
<td>CSL Behring AG</td>
<td>Wankdorfstrasse 10, 3014 Bern, Switzerland</td>
<td>System for Plasma Identification (SPI), version - 3.1.0</td>
<td>08-JUN-2011</td>
<td>CSL Behring AG</td>
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BK120002-0  CSL Plasma
900 Broken Sound Parkway
Suite 400
Boca Raton, FL 33487
Trade Name: LOGIC version 3.0.0
Cleared Date: 24-APR-2012
Cleared Under Haemonetics Corporation

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

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

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

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: 31-MAY-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

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

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

BK120008-0 Cascade Medical Enterprises, LLC
20 Greenup Court
Wayne, NJ 07470
Trade Name: FIBRINET (R) Autologous PRP System
Cleared Date: 01-AUG-2012

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Trade Name: COBE Spectra Single-Needle
Extended Life Platelet (ELP) Set
Cleared Date: 06-APR-1993

Trade Name: COBE Spectra Apheresis System
(Triple Platelet)
Cleared Date: 27-JUL-1994

Trade Name: COBE Spectra Version 4
Cleared Date: 20-SEP-1994

Trade Name: COBE Spectra Extended Life Platelet Set
Cleared Date: 15-FEB-1996

Trade Name: Donor Information System - 1.0
Cleared Date: 09-APR-1997

Trade Name: CBC Blood System, Version 1.2
Cleared Date: 20-NOV-1997

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

Trade Name: CONTINENTAL REFRIG. BLD.BNK. MODEL
C-BBRA-1S
Cleared Date: 17-JUL-1992

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

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

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

BK850008-0  Cooper Biomedical
            1 Technology Court
            Malvern, PA 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  Cryo-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

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

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

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

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

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

BK020057-0  Data Innovations Inc.
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 Inc.
120 Kimball Ave., Suite 100
South Burlington, VT 05430
Trade Name: Instrument Manager - 8.05.01.10
Cleared Date: 05-JAN-2007

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

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

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

BK980031-0  Defense Blood Standard System
5205 Leesburg Pike
Suite 1000
Falls Church, VA 22041
Trade Name: DBSS - 3.00
Cleared Date: 31-AUG-1998
Cleared Under Department of Defense

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

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

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

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

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

BK840001-0  Dia Tech
2525 Shader Road
Orlando, FL 328
Trade Name: DIACENT 1, Automated Cell Washer/Centrifuge
Cleared Date: 19-MAR-1984

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

BK120043-0  Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
BK120044-0  Diagnostic Grifols, S. A.
Passeig Fluvial, 24
Barcelona
Parets Del Valles, Spain 08150
Trade Name: Grifols Diluent
Cleared Date: 19-JUL-2013

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

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

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

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

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

BK110036-0  Diaspect Medical GMBH
800 E. Leigh Street
Suite 206-5
Richmond, VA 23219
Trade Name: DiaSpect Hemoglobin T and DiaSpect Hemoglobin Cuvettes
Cleared Date: 01-NOV-2011
BK120052-0 Diaspect Medical GMBH
800 E. Leigh Street
Suite 206-5
Richmond, VA 23219
Trade Name: DiaSpect Control HBT (-L, -M. -H)
Cleared Date: 14-NOV-2012

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK910015-0 Engineering & Research Associates, Inc.
500 North Tucson Boulevard (ERA Plaza)
Tucson, AZ 85716
Trade Name: Sebra Model #1290, Blood/Platelet Coolant
Cleared Date: 11-SEP-1991

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

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

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

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

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

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

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

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

BK830009-0 Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Plasma-Gard
Cleared Date: 25-JAN-1984
Cleared Under Travenol Laboratories
BK860015-0  Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Apheresis Kit/Extended Plate. Stor. & Plas. Coll.
Cleared Date: 03-JUL-1986
Cleared Under Travenol Laboratories

BK860029-0  Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Isoradial Separation Chamber
Cleared Date: 28-NOV-1986
Cleared Under Travenol Laboratories

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

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

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

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

BK900016-0  Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Closed System Apheresis Kit CS-3000 Blood Cell Separator (single venous access for platelet collection)
Cleared Date: 07-JUN-1991
Cleared Under Baxter Healthcare Corporation
Trade Name: Optum Platelet Separation Chamber
Cleared Date: 07-NOV-1990
Cleared Under Baxter Healthcare Corporation

Trade Name: Sepacell R-200; Pre-Storage Leukocyte Depletion Set for Red Blood
Cleared Date: 18-SEP-1991
Cleared Under Baxter Healthcare Corporation

Trade Name: OptiPress
Cleared Date: 03-JUN-1993
Cleared Under Baxter Healthcare Corporation

Trade Name: Fenwal Needle/Tube Sampling Protector/Safety Cover
Cleared Date: 12-MAR-1992
Cleared Under Baxter Healthcare Corporation

Trade Name: 30-mL Collection Chamber for CS-3000 Plus Blood Cell Separator
Cleared Date: 06-MAY-1994
Cleared Under Baxter Healthcare Corporation

Trade Name: Sepacell Pre-storage Leukocyte Depletion Set for Red Cell
Cleared Date: 07-JUN-1993
Cleared Under Baxter Healthcare Corporation

Trade Name: Closed System Apheresis Kit with Integral Leukocyte Removal Filter
Cleared Date: 27-JUL-1994
Cleared Under Baxter Healthcare Corporation

BK930029-0  Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: AccessTM Management System (AMS)  
Cleared Date: 20-JUN-1994  
Cleared Under Baxter Healthcare Corporation

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

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

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

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

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

BK940040-0  Fenwal Inc  
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Sepacell PLS-10A,5A Leukocyte Reduction Filter Platelet Products
Cleared Date: 28-FEB-1995
Cleared Under Baxter Healthcare Corporation

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

BK950013-0  Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: CS-3000 Plus (mononeuclear cells)
Cleared Date: 28-OCT-1998
Cleared Under Baxter Healthcare Corporation

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

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

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

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

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

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

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

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

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

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

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

Division

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

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

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

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

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

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

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

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

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

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

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

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

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

BK100041-0  Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: Autopheresis - C Plasmapheresis System
Cleared Date: 05-AUG-2010
BK100050-0  Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: Autopheresis-C Plasmapheresis system
Cleared Date: 16-NOV-2010

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

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

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

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

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

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

BK130004-0  Fenwal Inc
Three Corporate Dr
Lake Zurich, IL 60047

Trade Name: Alyx Component Collection System
Cleared Date: 11-SEP-2013

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

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: PLASMALINK
Cleared Date: 22-AUG-2008
Cleared Under Fenwal Blood Technologies

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

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

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

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

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

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.

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

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

BK040076-0  Fresenius Medical Care North America
95 Hayden Avenue
Lexington, MA 02420-9192
Trade Name: Compodock
Cleared Date: 17-DEC-2004
Cleared Under Fresenius Hemocare Inc.
BK880007-0 Fresenius USA/Seratronics Inc.
2637 Shadelands Drive
Walnut Creek, CA 94598
Trade Name: Fresenius AS104 Cell Separator
Cleared Date: 22-JUL-1996

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK830014-0  Gamma Biologicals, Inc.  
       3700 Mangum Road  
       Houston, TX 77092  
Trade Name: Elu-Kit II  
Cleared Date: 25-NOV-1983
Gamma Biologicals, Inc.
3700 Mangum Road
Houston, TX 77092
Trade Name: Gamma Microtear System
Cleared Date: 21-SEP-1983

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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
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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**BK960006-0**  
Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Double Unit Red Blood Cell 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

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

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

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

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

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

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

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

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

BK020001-0 Haemonetics Corporation
Trade Name: Plasma Pooling Bottle II
Cleared Date: 29-MAR-2002

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

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

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

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

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

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

Trade Name: PCS2 Plasma Collection System
Cleared Date: 02-JUN-2004
Braintree, MA 02184-9114
Trade Name: Haemonetics MCS+8150 Apheresis System
Cleared Date: 12-JUL-2004

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

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

BK050047-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: MCS+9000, SDP revision E software, 994CF-CPP series disposable sets
Cleared Date: 21-NOV-2005

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK080001-0  Haemonetics Corporation Software Solutions  
1630 Industrial Park Street  
Covina, CA 91722-9144  
Trade Name: PCS2 Plasma Collection System Revision K software  
Cleared Date: 28-MAY-2008  
Cleared Under Haemonetics Corporation

BK080038-0  Haemonetics Corporation Software Solutions  
1630 Industrial Park Street  
Covina, CA 91722-9144
Trade Name: MCS+ 9000 System  
Cleared Date: 04-SEP-2008  
Cleared Under Haemonetics Corporation

BK090004-0  
Haemonetics Corporation Software Solutions  
1630 Industrial Park Street  
Covina, CA 91722-9144  
Trade Name: MCS+8150 System - Wireless  
Cleared Date: 20-FEB-2009  
Cleared Under Haemonetics Corporation

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

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

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

BK820014-0  
Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Plasma Pooling Bags  
Cleared Date: 08-FEB-1983  
Cleared Under Cutter Biological

BK840010-0  
Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: CLX Transfer Bag  
Cleared Date: 15-AUG-1984  
Cleared Under Cutter Biological

BK850026-0  
Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Neocel System  
Cleared Date: 22-MAY-1986  
Cleared Under Miles, Inc.
BK860001-0  Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Leukotrap System  
Cleared Date: 05-AUG-1986  
Cleared Under Cutter Biological

BK860006-0  Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Cutter PPP Harness  
Cleared Date: 17-SEP-1986  
Cleared Under Miles, Inc.

BK860028-0  Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Component Aliquot System  
Cleared Date: 07-DEC-1987  
Cleared Under Miles, Inc.

BK860040-0  Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Blood Collection Unit w/o Anticoagulant  
Cleared Date: 24-JUN-1987  
Cleared Under Cutter Biological

BK900034-0  Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Phlebotomist Protection Device  
Cleared Date: 27-JAN-1992  
Cleared Under Miles, Inc.

BK920027-0  Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Plasma Pooling Bag  
Cleared Date: 13-APR-1993  
Cleared Under Miles, Inc.

BK930001-0  Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Plasma Sample Vial  
Cleared Date: 20-SEP-1993  
Cleared Under Miles, Inc.

BK970040-0  Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Medsep Plasma Bag
Cleared Date: 23-JAN-1998
Cleared Under MEDSEP Corp.

BK000032-0 Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Modified Plasma Bag
Cleared Date: 27-SEP-2000
Cleared Under MEDSEP Corp.

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

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

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

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

BK050074-0 Haemonetics Manufacturing Inc.
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

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
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

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

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 Capitol Drive, Suite 9
Research Triangle Park
Durham, NC 27713
Trade Name: C3 Control Cells
Cleared Date: 24-OCT-2012

BK140161-0  Hemo bioscience
801 Capitol Drive, Suite 9
Research Triangle Park
Durham, NC 27713
Trade Name: HemoQC
Cleared Date: 08-SEP-2014
BK060048-0  HemoCue AB
Kuvettgatan 1
Angelholm, Sweden SE-262 71
Trade Name: HemoCue Hb 301 System
Cleared Date: 05-OCT-2006

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

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

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

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

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

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

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

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

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

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

BK030087-0 ITL Corporation Pty, Ltd
41-45 Tennant Street
Canberra ACT 2609, Australia
Trade Name: ITL SampLok Sampling Kit
Cleared Date: 18-FEB-2004

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

BK130075-0 Immucor Transplant Diagnostics, Inc.
550 West Avenue
Stamford, CT 06902-6352
Trade Name: LIFECODES HLA-A SSO Typing Kit for use with Luminex
LIFECODES HLA-A eRES SSO Typing Kit for use with Luminex
LIFECODES HLA-B SSO Typing Kit for use with Luminex
LIFECODES HLA-B eRES SSO Typing Kit for use with Luminex
LIFECODES HLA-C eRES SSO Typing Kit for use with Luminex
LIFECODES HLA-DQB SSO Typing Kit for use with Luminex
LIFECODES HLA-DRB1 SSO Typing Kit for use with Luminex
LIFECODES HLA-DRB1 eRES SSO Typing Kit for use with Luminex

Cleared Date: 24-DEC-2013

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

BK830018-0 Immcucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Anti-A1 Lectin
Cleared Date: 07-NOV-1983

BK840024-0 Immcucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: corQc Test System
Cleared Date: 08-NOV-1984

BK860017-0 Immcucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture P Solid Phase System
Cleared Date: 06-OCT-1986

BK880010-0 Immcucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R (I and II)
Cleared Date: 03-JUN-1988

BK880011-0 Immcucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R (Pooled)
Cleared Date: 03-JUN-1988

BK880014-0 Immcucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Modified Capture-P
Cleared Date: 08-DEC-1988

BK880015-0 Immcucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-P Platelets Wash & Storage Solution
Cleared Date: 08-DEC-1988

BK880022-0  Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture P Ready Screen Solid Phase Assay
Cleared Date: 03-MAY-1989

BK890012-0  Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture R Ready Screen (Pooled)
Cleared Date: 21-JUN-1990

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

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

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

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

BK950017-0  Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture S
Cleared Date: 24-OCT-1997
BK950029-0  Immucor, Inc.
            3130 Gateway Drive
            P.O. Box 5625
            Norcross, GA 30091-5625
Trade Name: Capture - CMV
Cleared Date: 22-DEC-1995

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

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

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

BK960019-0  Immucor, Inc.
            3130 Gateway Drive
            P.O. Box 5625
            Norcross, GA 30091-5625
Trade Name: ABS2000
Cleared Date: 30-JUN-1998

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Trade Name: corQC Extend
Cleared Date: 28-SEP-2007

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

Trade Name: Galileo Automated Blood Bank System with assays to perform red blood cell phenotyping
Cleared Date: 28-SEP-2007

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

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

Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Trade Name: Galileo with Reverse ABO Group Assay
Cleared Date: 30-NOV-2007

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

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

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

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

Trade Name: FMH RapidScreen
Cleared Date: 22-MAY-2012

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK910018-0 International Specialty Products
1361 Alps Road
Wayne, NJ 07470
Trade Name: RAD-SURE BLOOD IRRADIATION LABEL
Cleared Date: 12-MAR-1992

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

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

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

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

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

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

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

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

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

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

BK890027-0  Jouan, Inc.  
Route 8, Box 1202; P.O. Box 2716  
Winchester, VA 22601  
Trade Name: Model KR4-22 Centrifuge  
Cleared Date: 02-FEB-1990

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

BK040035-0  Korchek Technologies, LLC  
770 Plattsville Road  
Trumbull, CT 06611
<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Cleared Date</th>
<th>Company Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>CareChek Patient Identification System, CareChek TX - version 1</td>
<td>12-AUG-2005</td>
<td>Kowa Company, Ltd. c/o Quintiles Consulting 1801 Rockville Pike, Suite 300 Rockville, MD 20852</td>
</tr>
<tr>
<td>LD-2000 Leukocyte Counter</td>
<td>14-JUN-2004</td>
<td>Lab 21 Healthcare Ltd 184 Cambridge Science Park Cambridge, Cambridgeshire United Kingdom CB4 0GA, UK</td>
</tr>
<tr>
<td>Lab 21 TPHA QC Kit</td>
<td>03-AUG-2010</td>
<td>Lab-Line Instruments, Inc. 15th and Bloomingdale Avenues Melrose Park, IL 60160</td>
</tr>
<tr>
<td>Hema-Bath</td>
<td>02-MAR-1987</td>
<td>Lattice, Inc. 1751 South Naperville Rd Suite 100 Wheaton, IL 60189</td>
</tr>
<tr>
<td>MediCopia Transfusion - v4.1</td>
<td>06-JAN-2012</td>
<td>Level 1 Technologies, Inc. 160 Weymouth Street Rockland, MA 02370</td>
</tr>
<tr>
<td>Level 1 Fluid Warmer</td>
<td>25-SEP-1986</td>
<td>Level 1 Technologies, Inc. 160 Weymouth Street Rockland, MA 02370</td>
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<tr>
<td>A/V Rewarming Procedural Kit Gentilello Technique</td>
<td>29-JAN-1993</td>
<td>Level 1 Technologies, Inc. 160 Weymouth Street Rockland, MA 02370</td>
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<tr>
<td>Level I Fluid Warmer</td>
<td>27-DEC-1994</td>
<td>Level 1 Technologies, Inc. 160 Weymouth Street Rockland, MA 02370</td>
</tr>
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<td>level 1 fluid warming system</td>
<td>16-JUN-2003</td>
<td>Level 1 Technologies, Inc. 160 Weymouth Street Rockland, MA 02370</td>
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</tbody>
</table>
BK070038-0  Life Technologies Corporation  
9099 North Deerbrook Trail  
Brown Deer, WI 53223  
Trade Name: AllSet Gold SSP  
Cleared Date: 26-SEP-2007  
Cleared Under Invitrogen Corporation

BK070041-0  Life Technologies Corporation  
9099 North Deerbrook Trail  
Brown Deer, WI 53223  
Trade Name: DynaChip HLA Antibody Analysis System  
Cleared Date: 30-APR-2008  
Cleared Under Invitrogen Corporation

BK070046-0  Life Technologies Corporation  
9099 North Deerbrook Trail  
Brown Deer, WI 53223  
Trade Name: UniMatch Plus Version 4.0  
Cleared Date: 27-SEP-2007  
Cleared Under Invitrogen Corporation

BK110038-0  Life Technologies Corporation  
9099 North Deerbrook Trail  
Brown Deer, WI 53223  
Trade Name: SeCore HLA Sequencing System  
 uType Dx HLA Analysis Software v1.0  
Cleared Date: 05-FEB-2013

BK110039-0  Life Technologies Corporation  
9099 North Deerbrook Trail  
Brown Deer, WI 53223  
Trade Name: 3500 Dx/3500 xL Dx Genetic Analyzer 8 CS2 and 3500 Dx Series Software  
Cleared Date: 05-FEB-2013

BK080017-0  LifeSouth Community Blood Centers Inc.  
4039 W. Newberry Road  
Gainesville, FL 32607  
Trade Name: Integrated Blood Bank Information System (IBBIS) Registration Module - v1.0  
Cleared Date: 05-AUG-2008

BK090064-0  LifeSouth Community Blood Centers Inc.  
4039 W. Newberry Road  
Gainesville, FL 32607  
Trade Name: Integrated Blood Bank Information System  
Cleared Date: 08-DEC-2009
BK130054-0  LifeSouth Community Blood Centers Inc.  
4039 W. Newberry Road  
Gainesville, FL 32607  
Trade Name: Integrated Blood Bank Information System, version 3.0 (IBBIS)  
Cleared Date: 17-JAN-2014

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

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

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

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

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

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

BK080002-0  MAK-System  
10 Avenue de la Grande Armee  
75017 Paris, France 75017  
Trade Name: ePROGES'A - 5.0.1  
Cleared Date: 13-MAY-2008
BK960029-0  MEDITECH Medical Information Technology, Inc.  
MEDITECH Circle  
Westwood, MA 02090  
Trade Name: MEDITECH  
Cleared Date: 19-MAR-1999

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK920031-0  Medical Marketing Consultants
3 Bethesda Metro Center, Suite 750
Bethesda, MD 20814
Trade Name: sHLA-STAT B27 ELISA for HLA-B27 Typing
Cleared Date: 20-AUG-1993
BK140092-0 Medion Grifols Diagnostics AG
Bonnstrasse 9
Duedingen,
Trade Name: DG Gel Extended Control
Cleared Date: 11-APR-2014

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

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

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

BK030078-0 Mediware Information Systems, Inc.
4545 Fuller Drive, Ste 320
Irving, TX 75038
Trade Name: HCLL - 2.6
Cleared Date: 08-APR-2004

BK040047-0 Mediware Information Systems, Inc.
4545 Fuller Drive, Ste 320
Irving, TX 75038
Trade Name: Instrument Interface Engine - 1.0
Cleared Date: 16-JUL-2004

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

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

BK080049-0 Mediware Information Systems, Inc.
1900 Spring Road, Suite 450
Oak Brook Service Center
Oak Brook, IL 60523
Trade Name: HCLL Transfusion, v3.0
Cleared Date: 22-OCT-2008

BK120036-0  Mediware Information Systems, Inc.
            1900 Spring Road, Suite 450
            Oak Brook Service Center
            Oak Brook, IL 60523
            Trade Name: HCLL(TM) Transfusion 2012
            Cleared Date: 19-SEP-2012

BK120039-0  Mediware Information Systems, Inc.
            1900 Spring Road, Suite 450
            Oak Brook Service Center
            Oak Brook, IL 60523
            Trade Name: LifeTrak(R) 2012
            Cleared Date: 05-SEP-2012

BK910019-0  Medsep Corporation
            2200 Northern Boulevard
            East Hills, NY 11548-1289
            Trade Name: Pall BPF4B Leukocyte Removal Blood
                        Processing Filter with Attached
                        Tubing and Blood Bag
            Cleared Date: 16-JAN-1992
            Cleared Under Pall Bio Medical

BK920023-0  Medsep Corporation
            2200 Northern Boulevard
            East Hills, NY 11548-1289
            Trade Name: Pall Autostop Leukocyte Removal
                        Platelet Filter with Tubing
            Cleared Date: 26-OCT-1992
            Cleared Under Pall Bio Medical

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

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

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

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

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

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

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

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

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

BK060014-0  Mosum Technology India PVT LTD  
55 Northern Blvd, Suite 200  
Great Neck, NY 11021  
Trade Name: PowerBANK Enterprise Edition - version 1.0  
Cleared Date: 30-MAR-2007

BK920024-0  Murex Biologicals, Inc.  
1107 I-45 South  
Conroe, TX 77301  
Trade Name: Murex PEG Potentiator for Antibody
Detection
Cleared Date: 01-JUN-1993

BK910016-0 NPBI
Runde ZZ 41, 7881 HM Emmer Compascuum
Emmer-Compascumm, Netherlands
Trade Name: Compomat
Cleared Date: 30-MAR-1992

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

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

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

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

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

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

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

BK120068-0 Nanoentek, Inc.
300 Washington St., STE 416
Newton, MA 02458
Trade Name: ADAM-rWBC
Cleared Date: 05-DEC-2012

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

BK840016-0 Neocyte
199 Weymouth Street
Rockland, MA 02370
Trade Name: NEOPACK System
Cleared Date: 25-JUN-1985

BK050032-0 Neoteric Technology Ltd
205-1099 W. 8th Ave.
Vancouver, British Columbia Canada V6H 1C3
Trade Name: BloodTrack SafeTx – Version 2.0
Cleared Date: 16-AUG-2005

BK050059-0 Neoteric Technology Ltd
205-1099 W. 8th Ave.
Vancouver, British Columbia Canada V6H 1C3
Trade Name: BloodTrack Courier – 3.2
Cleared Date: 13-DEC-2005

BK060041-0 Neoteric Technology Ltd
205-1099 W. 8th Ave.
Vancouver, British Columbia Canada V6H 1C3
Trade Name: BloodTrack – 4.1
Cleared Date: 12-OCT-2006

BK920020-0 Nor-Lake, Inc.
Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name: NSBR211, NSBR482, and NSB763 Blood Refrigerators
Cleared Date: 19-JAN-1993

BK930002-0 Nor-Lake, Inc.
Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name: NSBR61 (Nor-Lake Scientific Blood Bank, 6ft Single Door)
Cleared Date: 13-APR-1995

BK930003-0 Nor-Lake, Inc.
Second and Elm Str. P.O. Box 248
Hudson, WI 54016
Trade Name: NSBR83 (Nor-Lake Scientific Blood Bank, 8ft Double Door)
Cleared Date: 13-APR-1995

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

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

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

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

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

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

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

BK110060-0  Novartis Vaccines and Diagnostics, Inc.
4560 Horton St.
Emeryville, CA 94608-2916
Trade Name: PROCLEIX® NAT TRACKER® Version 3.0
Software
Cleared Date: 01-DEC-2011
BK930023-0  Nu-Quest, Inc.
1031 Meadowview Drive
Webb City, MO 64870
Trade Name: Little Pig Sticker
Cleared Date: 24-FEB-1994

BK830017-0  Nuclear-Medical Laboratories, Division
1800 Hurd Drive
Irving, TX 75061
Trade Name: Hepa-SHure
Cleared Date: 07-OCT-1983

BK080022-0  Olerup SSP AB
Hasselstigen 1
SE 133 33 Saltsjobaden
, Sweden
Trade Name: Olerup SSP HLA Typing Kits
Cleared Date: 20-FEB-2009

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

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

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

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

BK040003-0  Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: Olympus PK7200 Automated
Microplate System
Cleared Date: 06-FEB-2004
BK040070-0 Olympus America Inc., Diagnostic Systems Division
3131 West Royal Lane
Irving, TX 75063-3104
Trade Name: Tango Automated Blood Bank Analyzer System
Cleared Date: 22-MAR-2005

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

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

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

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

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

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

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

BK140093-0 Omrix Biopharmaceuticals Ltd.
PO Box 151, Route22 West
Somerville, NJ 08876-0151
Trade Name: Evicel Application Device
Cleared Date: 03-SEP-2014

BK120014-0 One Lambda, Inc
21001 Kittridge St
Canoga Park, CA 91303
Trade Name: HLA Fusion Software, Version 3.0
Cleared Date: 18-DEC-2012

BK120024-0 One Lambda, Inc
21001 Kittridge St
Canoga Park, CA 91303
Trade Name: LABType (R) SSO DNA Typing Tests for use with LABScanTM 3D
Cleared Date: 20-DEC-2012

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

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

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

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

BK920009-0 One Lambda, Inc.
21001 Kittridge St.
Canoga Park, CA 91303
Trade Name: Anti-B27 FITC Conjugated Monoclonal Antibody
Cleared Date: 25-MAR-1993

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

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

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

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

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

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

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

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

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

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

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

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

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

BK030036-0 OriGen BioMedical
4020 S. Industrial Dr. #160
Austin, TX 78744
Trade Name: OriGen Cryostore Freezing Bags
Cleared Date: 01-OCT-2003

BK820003-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name: ORTHO Confidence System
Cleared Date: 10-AUG-1982

BK820006-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name: Simwash
Cleared Date: 13-APR-1983

BK830023-0 Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name: TYTEM Typing and Detection System
Cleared Date: 08-DEC-1983

BK840017-0  Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name: ORTHO Cell Suspension Tube
Cleared Date: 16-NOV-1984

BK890021-0  Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name: Ortho Confidence System
Cleared Date: 23-OCT-1989

BK920034-0  Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name: Ortho BioVue System
Cleared Date: 09-MAY-1995

BK960003-0  Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name: Ortho Summitt System
Cleared Date: 19-OCT-1998

BK960052-0  Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
P.O. Box 350
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
P.O. Box 350
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
P.O. Box 350
Raritan, NJ 08869-0606
Trade Name: Genetic Systems HIV-1/HIV-2 PLUS O
Ortho Assay Protocol Disk
Cleared Date: 03-NOV-2006

BK050046-0  Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202  
P.O. Box 350  
Raritan, NJ 08869-0606  
Trade Name: Genetic Systems HBsAg EIA 3.0  
Ortho Assay Protocol Disk  
Cleared Date: 13-JAN-2006

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

BK090074-0  
Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
P.O. Box 350  
Raritan, NJ 08869-0606  
Trade Name: Ortho Summit System  
Cleared Date: 27-MAY-2009

BK100040-0  
Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
P.O. Box 350  
Raritan, NJ 08869-0606  
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  
P.O. Box 350  
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  
P.O. Box 350  
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  
P.O. Box 350  
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
Trade Name: ORTHO VERSEIA® Integrated Processor (VIP)
Cleared Date: 23-MAY-2013

Trade Name: ORTHO (TM) Workstation
Cleared Date: 09-AUG-2013

Trade Name: Osteokin System
Cleared Date: 23-JUN-2004

Trade Name: Pall eBDS
Cleared Date: 13-FEB-2009
Cleared Under Pall Life Sciences

Trade Name: Patent Touch(TM) Blood Product Administration System v3.2.1
Cleared Date: 13-NOV-2012

Trade Name: Leukocyte Typing Serum (Human) (Tray Package)
Cleared Date: 12-JAN-1983

Trade Name: Frozen Leukocyte Panel (Human)
Cleared Date: 01-AUG-1985

Trade Name: Leukocyte Typing Serum (Human)
Cleared Date: 12-JAN-1983
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

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

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

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

BK880029-0  Revco/Lindberg
275 Aiken Road
Asheville, NC 28804
Trade Name: MBF700 Blood Freezer
Cleared Date: 16-JUN-1989

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

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

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

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

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

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

BK020018-0  Roche Molecular Systems, Inc.  
    4300 Hacienda Drive  
    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

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

BK990008-0  Rubin & Poor, Inc.  
    155 Maplewood Avenue #5  
    Maplewood, NJ 07040  
    Trade Name: Rubin & Poor Configurable Manual Blot System - 1.0C  
    Cleared Date: 29-OCT-1999

BK000030-0  Rubin & Poor, Inc.  
    155 Maplewood Avenue #5  
    Maplewood, NJ 07040  
    Trade Name: Configurable Laboratory Result Manager (CLRM) - 1.0E  
    Cleared Date: 23-NOV-2001

BK030073-0  Rubin & Poor, Inc.  
    155 Maplewood Avenue #5  
    Maplewood, NJ 07040  
    Trade Name: Configurable Manual Batch Entry - 1.1A  
    Cleared Date: 14-JAN-2004

BK080028-0  Rubin & Poor, Inc.  
    155 Maplewood Avenue #5  
    Maplewood, NJ 07040  
    Trade Name: Pool results Manager
Cleared Date: 03-SEP-2008

BK050045-0  SCC Soft Computer
34350 U.S. Highway 19 North
Palm Harbor, FL 34684
Trade Name: SoftDonor 4.3 with SoftScape
Cleared Date: 26-OCT-2005

BK060059-0  SCC Soft Computer
34350 U.S. Highway 19 North
Palm Harbor, FL 34684
Trade Name: SoftDonor 4.4 with DMSI - 4.4
Cleared Date: 21-DEC-2006

BK080020-0  SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftBank II - v23.2
Cleared Date: 12-AUG-2008

BK080069-0  SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftDonor 4.5 - 4.5
Cleared Date: 16-JAN-2009

BK090017-0  SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftBank II Version 25 - 25
Cleared Date: 23-JUN-2009

BK090078-0  SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftID.Tx Version 1.0
Cleared Date: 28-APR-2010

BK100045-0  SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftBank II - 25.1
Cleared Date: 29-JUL-2010

BK140128-0  SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftBank Version 25.5
Cleared Date: 05-AUG-2014

BK950057-0  SG Scientific
5745 SW 75th Street
#284
Gainseville, FL 32608
Trade Name: The Saber (Segment Piercing Device)

Cleared Date: 13-NOV-1995

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

BK050052-0 STEMCO Biomedical, Inc.
2810 Meridan Parkway
Suite 148
Durham, NC 27713
Trade Name: 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

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

BK970037-0 SangStat Medical Corporation
6300 Dumbarton Circle
Freemont, CA 94555
Trade Name: PRA-STAT Anti-HLA CLASS I IgG Antibodies/Two Patients per Plate Format
Cleared Date: 18-NOV-1998

BK940011-0 Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name: Sanguin Medusa 2000
Cleared Date: 29-SEP-1994
BK960065-0  Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name: Sanguin Medusa 2000 - 3.4
Cleared Date: 17-DEC-1998

BK980003-0  Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name: Aurora/Fenestra (version 1.0)
Cleared Date: 29-SEP-1999

BK980039-0  Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name: Medusa 2000 Srimport, Version 1.2
Cleared Date: 11-JUN-1999

BK090061-0  Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name: Sanguin Aurora version 2.0
Cleared Date: 22-DEC-2009

BK100030-0  Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name: Sanguin Liberty SRIMPORT - 3.1
Cleared Date: 08-JUL-2010

BK010042-0  Sarstedt, Inc.
1025 Saint James Church Rd.
Newton, NC 20865
Trade Name: Transwaag KL
Cleared Date: 12-DEC-2001

BK010045-0  Sarstedt, Inc.
1025 Saint James Church Rd.
Newton, NC 20865
Trade Name: Sahara Blood & Plasma Warming Device
Cleared Date: 21-DEC-2001

BK030006-0  Sarstedt, Inc.
1025 Saint James Church Rd.
Newton, NC 20865
Trade Name: Transwaag Disk 01
Cleared Date: 27-FEB-2003

BK040080-0  Sarstedt, Inc.
1025 Saint James Church Rd.
Newton, NC 20865
Trade Name: Sahara-TSC
Cleared Date: 09-FEB-2005
BK070029-0 Sarstedt, Inc.
1025 Saint James Church Rd.
Newton, NC 20865
Trade Name: S-Monovette ACD-A
Cleared Date: 21-SEP-2007

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

BK870011-0 Seabrook Medical Systems, Inc.
673 Wilmer Avenue
Cincinnati, OH 45226
Trade Name: ECMO-TEMP
Cleared Date: 14-SEP-1987

BK820005-0 Separation Science Corporation
169 Avon Street, P.O. Box 643
Stratford, CT 06497
Trade Name: SEPCOR Cell Line Monitor
Cleared Date: 06-JUL-1982

BK880005-0 Separation Science Corporation
169 Avon Street, P.O. Box 643
Stratford, CT 06497
Trade Name: Blood Bank Saline, Preserved
Cleared Date: 09-JUN-1988

BK050056-0 Separation Technology, Inc.
1096 Rainier Drive
Altamonte Springs, FL 32714-3855
Trade Name: UltraChek Reference Controls - Product Code GLK
UltraCritTM Hematocrit Measurement Device - Product Code GKF
Cleared Date: 12-DEC-2005

BK960036-0 Shared Medical Systems
51 Valley Stream Parkway
Malvern, PA 19355
Trade Name: SMS BB Transfusion System
Cleared Date: 12-DEC-1997

BK990018-0 Shotwell & Carr, Inc.
3535 Firewheel Drive
Suite A
Flower Mound, TX 75028-2628
Trade Name: Hot Shot Fluid Warmer Model 100
Hot Shot Fluid Warmer Model 101
Hot Shot Fluid Warmer Model 102
Hot Shot Fluid Warmer Model 103
Cleared Date: 13-OCT-1999

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

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

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

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

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

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

BK060015-0 Siemens Medical Solutions Diagnostics
P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 21-MAR-2006
Cleared Under Bayer HealthCare Diagnostics Division

BK070009-0 Siemens Medical Solutions Diagnostics
P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 19-MAR-2007

BK080036-0 Siemens Medical Solutions Diagnostics
P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 20-OCT-2008

BK080073-0 Siemens Medical Solutions Diagnostics
P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 15-JAN-2009

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

BK040066-0 sienna partners
P.O. Box 103
Baldwin, MD 21013
Trade Name: Greiner VACUETTE No Additive Evacuated Blood Collection Tubes and Serum Clot Activator Blood Collection Tubes
Cleared Date: 10-SEP-2004

BK060004-0 Smith & Nephew
1450 Brooks Road
Memphis, TN 38116
Trade Name: Promote Platelet Rich Concentrate (PRC) Preparation System
Cleared Date: 02-MAY-2006

BK850011-0 Smithkline Beckman Corp.
999 West Valley Road
Wayne, PA 19087
Trade Name: Accugenics (Tray)
Cleared Date: 07-AUG-1985
BK850012-0  Smithkline Beckman Corp.  
999 West Valley Road  
Wayne, PA 19087  
Trade Name: Accugenics (HLA Control Cells)  
Cleared Date: 07-AUG-1985

BK080047-0  SofTov Ltd  
32 HaShacham Street  
Petach Tikva, Israel 49170  
Trade Name: AutoFusion - v3.02  
Cleared Date: 05-JUN-2009

BK960033-0  Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftBank II Version 19.1  
Cleared Date: 10-JUL-1998

BK000040-0  Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftBank II - 21.2  
Cleared Date: 20-APR-2001

BK020006-0  Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftDonor - 4.1  
Cleared Date: 27-FEB-2003

BK020021-0  Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftBank II - 22  
Cleared Date: 11-SEP-2002

BK030018-0  Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftBank II - 23  
Cleared Date: 17-APR-2003

BK040028-0  Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftBank II with SoftScape - 23  
Cleared Date: 07-MAY-2004

BK040048-0  Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftBank II with Database Management System Interface (IMSI)
BK970032-0  Sorvall, Inc.
31 Pecks Lane
Newtown, CT 06470
Trade Name: RC12BP
Cleared Date: 05-DEC-1997

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

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

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

BK870015-0  Stephens Scientific
7 Astro Place Box 1116
Denville, NJ 07834
Trade Name: Certified Blood Bank Saline, Preserved
Cleared Date: 02-NOV-1987

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

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

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

BK990002-0 Sunquest Information Systems, Inc.
4801 Broadway Boulevard
Tucson, AZ 85711
Trade Name: Flexilab - 5.2
Cleared Date: 16-AUG-1999

BK990034-0 Sunquest Information Systems, Inc.
4801 Broadway Boulevard
Tucson, AZ 85711
Trade Name: FlexiLab Blood Bank and Blood Donor System - Version 5.2
Cleared Date: 17-NOV-1999

BK080021-0 Sunquest Information Systems, Inc.
250 S. Williams Blvd.
Tucson, AZ 85711
Trade Name: Sunquest Transfusion Manager - v1.0
Cleared Date: 03-DEC-2008

BK080042-0 Sunquest Information Systems, Inc.
250 S. Williams Blvd.
Tucson, AZ 85711
Trade Name: Sunquest Blood Bank Donor - 6.4
Cleared Date: 03-MAR-2009

BK140124-0 Sunquest Information Systems, Inc.
250 S. Williams Blvd.
Tucson, AZ 85711
Trade Name: Sunquest Transfusion Manager version 2.0
Cleared Date: 18-JUN-2014

BK120061-0 SynGen, Inc.
2125 19th Street, Suite 120
Sacramento, CA 95818
Trade Name: SynGenX-1000
Cleared Date: 12-JUL-2013

BK120067-0 SysLogic, Inc.
375 Bishops Way, Suite 105
Brookfield, WI 53005
Trade Name: iTrace for Blood Centers - 1.0.924.0
Cleared Date: 28-MAY-2013

BK960034-0 SysTec Computer Associates, Inc.
738 Smithtown Bypass
Smithtown, NY 11787
Trade Name: Lifetec Comm. Blood Center
BK990003-0  SysTec Computer Associates, Inc.
28 North Country Road
Mt. Sinai, NY 11766
Trade Name: LifeTec - 2.20
Cleared Date: 30-JUL-1999

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

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

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

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

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

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

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

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

BK120012-0 TERUMO Corporation
10811 W. Collins Avenue
Lakewood, CO 80215
Trade Name: Spectra Optia Apheresis System
Cleared Date: 09-JUL-2012

BK120017-0 TERUMO Corporation
10811 W. Collins Avenue
Lakewood, CO 80215
Trade Name: Trima Accel Automated Blood Component Collection System
Cleared Date: 31-MAY-2012

BK120040-0 TERUMO Corporation
10811 W. Collins Avenue
Lakewood, CO 80215
Trade Name: Trima Accel System
Cleared Date: 03-OCT-2012

BK120049-0 TERUMO Corporation
10811 W. Collins Avenue
Lakewood, CO 80215
Trade Name: Trima Accel System
Cleared Date: 17-DEC-2012

BK970012-0 Tahoe Chemical R & D
2230 Damon Road
Carson City, NV 89701
Trade Name: Nover Trip Scale Alarm
Cleared Date: 14-JUL-1997

BK040062-0 Talisman Ltd.
421 Church Street NE. Suite F
Vienna, VA 22180
Trade Name: Quality Donor System 2004 - 2.0
Cleared Date: 18-OCT-2004

BK060031-0 Talisman Ltd.
421 Church Street NE. Suite F
Vienna, VA 22180
Trade Name: Talisman Phlebotomy System Release 1.0
Cleared Date: 27-JUL-2006

BK070020-0 Talisman Ltd.
421 Church Street NE. Suite F
Vienna, VA 22180
Trade Name: Quality Donor System - v2.1
Cleared Date: 16-JUL-2007
BK980021-0  Talon Medical, Ltd.
18160 Highway 281 N
Suite 108
San Antonio, TX 78232
Trade Name: Cord-X System
Cleared Date: 20-JAN-1999

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

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

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

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

BK010037-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Platelet collection sets for the COBE Spectra Apheresis System and the Trima Automated Blood Component Collection System.
Cleared Date: 09-DEC-2002
Cleared Under Gambro BCT, Inc
BK010046-0  Terumo BCT, Inc
   10811 W. Collins Ave.
   Lakewood, CO 80215-4498
Trade Name: Trima Automated Blood Collection System (Single Stage)
Cleared Date: 18-SEP-2002
Cleared Under Gambro BCT, Inc

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

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

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

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

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

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

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

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

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

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

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

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

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

BK820015-0  Terumo Corporation  
2805 East Ana Street  
Compton, CA 90221  
Trade Name: Plasmaflex Pooling Bottle  
Cleared Date: 12-NOV-1982

BK850017-0  Terumo Corporation  
2805 East Ana Street  
Compton, CA 90221  
Trade Name: Plasmaflex Bottles  
Cleared Date: 04-NOV-1985

BK860012-0  Terumo Corporation  
2805 East Ana Street  
Compton, CA 90221  
Trade Name: Imugard Leukocyte Filter  
Cleared Date: 16-MAY-1990

BK890005-0  Terumo Corporation  
2805 East Ana Street  
Compton, CA 90221  
Trade Name: Stericell Cell Processor  
Cleared Date: 10-OCT-1989

BK890017-0  Terumo Corporation  
2805 East Ana Street  
Compton, CA 90221  
Trade Name: Teruflex Transfer Bag  
Cleared Date: 18-JUL-1990

BK890032-0  Terumo Corporation  
125 Blue Ball Road  
Elkton, MD 21921  
Trade Name: Immugard-E- Leukocyte Removal From Red Blood Cells  
Cleared Date: 18-JUL-1990

BK900028-0  Terumo Corporation
BK920040-0  Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name: Terufusion Plasma Transfer Set
Cleared Date: 22-OCT-1990

BK950039-0  Terumo Corporation
2100 Cottontail Lane
Somerset, NJ 08873
Trade Name: Teruflex B-600 Terumo Blood Bag without anticoagulant
Cleared Date: 25-AUG-1995

BK950058-0  Terumo Corporation
2100 Cottontail Lane
Somerset, NJ 08873
Trade Name: Terumo Sampling Site Coupler
Cleared Date: 13-NOV-1995

BK860041-0  Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: SCD 312
Cleared Date: 01-JUN-1987

BK970008-0  Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: Terumo Sterile Tubing Welder
SC-201A (TSCD)
Cleared Date: 28-MAY-1998

BK970011-0  Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: Terumo Phlebotomy Needle Cap Holder
Cleared Date: 19-JUN-1997

BK000045-0  Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: Imugard III-PL
Cleared Date: 28-SEP-2001

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

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

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

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

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

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

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

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

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

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

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

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

BK820012-0  UCLA Tissue Typing Laboratory
1000 Veteran Avenue
Los Angeles, CA 90024
Trade Name: HLA Typing Tray
Cleared Date: 04-MAR-1983

BK970026-0  Utah Medical Products, Inc.
7043 South 300 West
Midvale, UT 84047
Trade Name: Umbilicup
Cleared Date: 28-JAN-1998

BK970027-0  Utah Medical Products, Inc.
7043 South 300 West
Midvale, UT 84047
Trade Name: Umbilicup II Cord Blood System
Cleared Date: 06-JAN-1998

BK010043-0  VEEGEE Scientific
13600 NE 126th Place
Suite A
Kirkland, WA 98034
Trade Name: Atago SP-D2 Refractometer
Cleared Date: 02-JAN-2002

BK870008-0  Val Tech Diagnostics
14 Werner Camp Road
Pittsburgh, PA 15238
Trade Name: Normal Saline-Buffered
Cleared Date: 31-JUL-1987

BK880004-0  Val Tech Diagnostics
14 Werner Camp Road
Pittsburgh, PA 15238
Trade Name: Buffered Normal Saline Concentrate
Cleared Date: 11-APR-1988

BK070044-0  Verax Biomedical Incorporated
148 Bartlett Street
Marlborough, MA 01752
Trade Name: Platelet PGD Controls
Platelet PGD Test
Cleared Date: 17-SEP-2007

BK090028-0  Verax Biomedical Incorporated
148 Bartlett Street
Marlborough, MA 01752
Trade Name: Platelet PGD Test System
Cleared Date: 10-NOV-2009

BK110014-0  Verax Biomedical Incorporated
148 Bartlett Street
Marlborough, MA 01752
Trade Name: Platelet PGD Test System
Cleared Date: 08-SEP-2011

BK020005-0  Visible Genetics, Inc.
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 Canada
Trade Name: Trugene HIV-1 Genotyping Kit and Open Gene DNA Sequencing System
Cleared Date: 24-APR-2002

BK020042-0  Visible Genetics, Inc.
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 Canada
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 07-NOV-2002

BK030015-0  Visible Genetics, Inc.
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 Canada
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 14-MAR-2003

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

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

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: Safe Trace
Cleared Date: 14-APR-1997

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

**BK070010-0** Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: ElDorado Donor Doc - 1.0.0
Cleared Date: 23-MAY-2007

**BK070064-0** Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: ElDorado Donor - 1.0.0
Cleared Date: 13-FEB-2008

**BK090026-0** Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: Safe Trace Tx
Cleared Date: 03-SEP-2009

**BK090033-0** Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: ElDorado Donor Doc
Cleared Date: 28-OCT-2009

**BK090063-0** Wyndgate Technologies
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: Test Result Interface for ElDorado Donor
Cleared Date: 20-NOV-2009

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