Currently Cleared CBER 510(k)s by Applicant As of 31-AUG-2022

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

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

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

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

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

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

BK060051-0  5D Information Management
             Suite 500, 10025 - 102A Avenue
             Edmonton, Alberta Canada T5J 2Z2
             Trade Name: HaemoConnect (eLynx) - 1.0.0
             Cleared Date: 06-MAR-2008
BK070011-0  ABSORBER AB
Drottninggatan 33
Stockholm, SWEDEN SE-103 95
Trade Name: XM-ONE Transplantation Cross Match
Cleared Date: 29-JUL-2008

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

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

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

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

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

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

BK100005-0  ALBA Bioscience Limited (doing business as Quotient)
21 Ellen's Glen Road
Liberton, Edinburgh
EH17 7QT
Scotland, UNITED KINGDOM, UNITED KINGDOM EH17 7QT
Trade Name: ALBAcyte IgG Sensitized Red Blood Cells
Cleared Date: 26-AUG-2010
Cleared Under ALBA Bioscience

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

BK140208-0  ALBA Bioscience Limited (doing business as Quotient)
21 Ellen's Glen Road
Liberton, Edinburgh
EH17 7QT
Scotland, UNITED KINGDOM, UNITED KINGDOM EH17 7QT
Trade Name: ALBAcyte® C3 Coated Red Blood Cells
Cleared Date: 04-MAR-2015

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

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

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

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

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

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

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

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

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

BK190393-0  Aeon Biotherapeutics Corp.  
           12F., No.58, Ruihu St.  
           Taipei City, Neihu Dist TAIWAN 11494  
Trade Name: Aeon CPKit  
Autologous CellPrep Kit  
Cleared Date: 05-JUN-2020
BK170013-0  Alba Bioscience Limited
21 Ellen's Glen Rd
Edinburgh,
Trade Name: AlbaQ-Chek (R) Simulated Whole Blood Controls, Model Z498
Cleared Date: 09-MAY-2017

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

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

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

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

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

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

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

BK220713-0   Alma Lasers, Inc
485 Half Day Rd
Suite 100
Buffalo Grove, IL 60089
Trade Name: Alma LipoFlow System (K171242)
Cleared Date: 05-APR-2022

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-A1 Lectin
Cleared Date: 16-JUN-1986

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

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

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

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

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

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

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

BK220698-0  Andrew Technologies LLC
            3 Haddon Ave
            Haddonfield, NJ 08033
            Trade Name: HYDRASOLVE LIPOPLASTY SYSTEM
            (K130152)
            Cleared Date: 29-MAR-2022

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

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

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

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

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

BK170114-0  Arlington Scientific, Inc.
         1840 North Technology Dr.
         Springville, UT 84663
         Trade Name: ASI Evolution - 2800-000
         Cleared Date: 28-DEC-2017
BK200488-0  Arlington Scientific, Inc.
              1840 North Technology Dr.
              Springville, UT 84663
Trade Name: ASI Automated RPR test for
              Syphilis for use on the ASI
              Evolution
ASI Evolution
Cleared Date: 30-SEP-2020

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

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

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

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

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

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

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

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

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

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

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

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
BK190433-0  AuraGen Aesthetics LLC  
11 Dellbrook Rd  
Weston, MA 02493  
Trade Name: AuraGen 1-2-3™ with AuraClens™  
Suction Lipoplasty System (A123+AuraClens)  
Cleared Date: 13-MAR-2020

BK220717-0  AuraGen Aesthetics LLC  
11 Dellbrook Rd  
Weston, MA 02493  
Trade Name: AuraGen 123 Suction Lipoplasty System (A123) (K190278)  
Cleared Date: 05-APR-2022

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

BK150294-0  B.T.I Biotechnology Institute, S.L.  
Leonardo DaVinci 14  
Parque Tecnologico De Alava  
Minano, Alava SPAIN 01510  
Trade Name: ENDORET Kit  
Cleared Date: 09-DEC-2015

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

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

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

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

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

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

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

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

BK060022-0  BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name: ACCURUN 365 West Nile Virus RNA Positive Quality Control
Cleared Date: 12-JUN-2006
BK060030-0  BBI Diagnostics, A SeraCare Company
375 West Street
West Bridgewater, MA 02379
Trade Name: ACCURUN 804 Nucleic Acid Negative Quality Control (HIV, HCV, HBV, WNV)
Cleared Date: 18-AUG-2006

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

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

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

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

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

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

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

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

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

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

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

BK220715-0  BSL Co.
6-13, Chilsan-ro 237beon-gil
Gimhae-si, Gyeongsangnam-do KOREA, SOUTH 51006
Trade Name: Automatic Tissue Processing Unit (K172717)
Cleared Date: 05-APR-2022

BK220722-0  BSL Co.
6-13, Chilsan-ro 237beon-gil
Gimhae-si, Gyeongsangnam-do KOREA, SOUTH 51006
Trade Name: Smart Kit Basic, Smart Kit Pro (K202443)
Cleared Date: 07-APR-2022

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK140112-0  Bio-Rad Laboratories
6565 185th Ave NE
Clinical Diagnostics Group
Redmond, WA 98052-5039
Trade Name: BioPlex? 2200 System
Cleared Date: 23-JUL-2015

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

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

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

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

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

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

BK170019-0  Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: IH-1000 (Model# 001100)
Cleared Date: 05-MAY-2017

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

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

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

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

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

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

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

BK180175-0 Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
Dreieich, GERMANY 63303
Trade Name: TANGO Infinity
Cleared Date: 01-MAY-2018

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK220690-0  Biomet Biologics, Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587
Trade Name: FAT CONCENTRATION SYSTEM (K100114)
Cleared Date: 29-MAR-2022
Biometric Imaging, Inc.
1025 Terra Bella Avenue
Mountain View, CA 94043
Trade Name: CEQer RBC Assay
Cleared Date: 18-SEP-1998

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

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

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

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

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

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

Biotech Research Laboratories, Inc.
1600 East Gude Drive
Rockville, MD 20850
Trade Name: Run Control for HBsAg Assay
Cleared Date: 25-JAN-1985
BK090069-0  Biotechnology Institute, SL.
   C/Leonardo Da Vinci 14B, 1B.
   01510 Minano (Alava)
   Alava, SPAIN 01510
Trade Name: Endoret Kit
Secondary Product Code: FMI, GKT
Cleared Date: 01-FEB-2010

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

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

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

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

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

BK980033-0  Biotest Diagnostics Corporation
   66 Ford Road, Suite 131
   Denville, NJ 07834
Trade Name: LYMPHOSCREEN ABC 60
Cleared Date: 15-DEC-1999
BK980044-0  Biotest Diagnostics Corporation
66 Ford Road, Suite 131
Denville, NJ 07834
Trade Name: Lymphoscreen DR 30 x 2
Cleared Date: 15-DEC-1999

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

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

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

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

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

BK830027-0  Biotest-Serum-Institut GmbH
Flughafenstrasse 4
6000 Frankfurt/Main 73, GERMANY
Trade Name: Microtest Testing Tray (HLA-DR Wells)
Cleared Date: 26-APR-1984
BK170150-0  Biowy Corporation
27031 Vista Terrace
Lake Forest, CA 92630
Trade Name: Biowy Freezing Bag FB1000
Biowy Freezing Bag FB250
Biowy Freezing Bag FB50
Biowy Freezing Bag FB500
Cleared Date: 11-MAY-2018

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK160011-0  Blood Bank Computer Systems, Inc.
        1002 15th St. SW, Suite 120
        Auburn, WA 98001-6502
Trade Name: ABO Express - Model 2.0.0
Cleared Date: 26-APR-2016
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: 12-NOV-2002
Cleared Under COBE BCT

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

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

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

BK980004-0  COBE Cardiovascular, Inc.
            1201 Oak Street
            Lakewood, CO 80215
Trade Name: COBE Spectra Apheresis System
            Anticoagulant Free Flow
            Restriction
Cleared Date: 09-JUL-1998
Cleared Under COBE BCT
BK990025-0  COBE Cardiovascular, Inc.
1201 Oak Street
Lakewood, CO 80215
Trade Name: Cobe Trima
Cleared Date: 07-APR-2000
Cleared Under COBE BCT

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

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

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

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

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

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

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

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

BK190430-0  CSL Plasma
900 Broken Sound Parkway
Suite 400
Boca Raton, FL 33487
Trade Name: Anti-D Donor Management and Inventory System (ADIMS) - Version 1.7
Cleared Date: 11-MAR-2020

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

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

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

BK120035-0  Calimex USA Corporation
258 Hollister Avenu
Alameda, CA 94501
Trade Name: Picture-ID Version 2.0
Cleared Date: 17-DEC-2012
Cardiovascular Dynamics, Inc.
15 Hammond Suite 307
Irvine, CA 92718
Trade Name: CVD Bullett Infusion Catheter
Cleared Date: 27-FEB-1995

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

Care Fusion, Inc.
1430 Spring Hill Road, Suite 510
McLean, VA 22102
Trade Name: wBlood Care - 1.0
Cleared Date: 10-NOV-2004

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

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

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

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

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

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

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

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

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

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

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

BK200491-0  Carter BloodCare
2205 Highway 121
Bedford, TX 76021
Trade Name: iWeBB electronic Laboratory Information System (iWeBB-eLIS)
Cleared Date: 29-JUL-2020
BK200514-0  Cartiva, Inc.
6120 Windward Pkwy
Alpharetta, GA 30005
Trade Name: Cartiva SCI Disposable Instrumentation set
Cleared Date: 14-AUG-2020

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

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

BK06006-0  Cascade Medical Enterprises, LLC
20 Greenup Court
Wayne, NJ 07470
Trade Name: Cascade Medical FIBRINET System
Cleared Date: 16-FEB-2006

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK060037-0  Cerner Corporation
            2800 Rock Creek Parkway
            Kansas City, MO 64117-2551
            Trade Name: Cerner Bridge Medical Transfusion Administration and Specimen Collections - 3.3
            Cleared Date: 24-MAY-2007
BK860025-0  Cetus Corporation
1400 53rd Street
Emeryville, CA 94608
Trade Name: Pro Group System
Cleared Date: 27-APR-1987

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK970007-0  Community Bio-Resources, Inc.
2197 Parkway Lake Drive
Hoover, AL 35244
Trade Name: Donor Information System - 1.0
Cleared Date: 09-APR-1997
BK960060-0  Community Blood Center of Greater Kansas City  
             4040 Main Street  
             Kansas City, MO 64111  
             Trade Name: CBC Blood System, Version 1.2  
             Cleared Date: 20-NOV-1997

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

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

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

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

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

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

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

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

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

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

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

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

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

BK840012-0  Cryosan Inc.
            850 Providence Highway
            Dedham, MA 02026
            Trade Name: BT 765 Elutriation Pump
            Cleared Date: 06-FEB-1985
BK870003-0  Cryosan Inc.
            850 Providence Highway
            Dedham, MA 02026
            Trade Name: Cryo-PakTM System
            Cleared Date: 17-APR-1987

BK960012-0  CytoTherm LP
            110 Sewell Avenue
            Trenton, NJ 08610
            Trade Name: Cyto Therm (T-S)
            Cleared Date: 15-APR-1996
            Cleared Under Photo-Therm

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

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

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

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

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

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

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

BK220684-0  Cytori Therapeutics Inc.
            3020 Callan Road
            San Diego, CA 92121
Trade Name: CYTORI AFT SYSTEM
            CYTORI AFT SYSTEM (K072587)
Cleared Date: 28-MAR-2022

BK220689-0  Cytori Therapeutics Inc.
            3020 Callan Road
            San Diego, CA 92121
Trade Name: CYTORI PUREGRAFT 250/PURE SYSTEM
            (K092923)
            FAT CONCENTRATION SYSTEM (K100114)
Cleared Date: 28-MAR-2022

BK220693-0  Cytori Therapeutics Inc.
            3020 Callan Road
            San Diego, CA 92121
Trade Name: PUREGRAFT 850/PURE SYSTEM
            (K113255)
Cleared Date: 29-MAR-2022

BK220699-0  Cytori Therapeutics Inc.
            3020 Callan Road
            San Diego, CA 92121
Trade Name: PUREGRAFT 50 SYSTEM (K132815)
Cleared Date: 29-MAR-2022

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

BK990022-0  Denco, Inc.
            P.O.Box 9600
            Wilmington, DE 19809
Trade Name: Total Containment Device
Cleared Date: 18-APR-2000

BK990041-0  Denco, Inc.
Trade Name: Total Containment Device
Cleared Date: 21-DEC-1999

Trade Name: Neg Control
Cleared Date: 02-FEB-2018

Trade Name: PK SYSTEM CONTROL
Cleared Date: 07-MAY-2020

Trade Name: DSM Biomedical PRP Device
Cleared Date: 25-MAR-2014

Trade Name: The JEN Device
Cleared Date: 06-MAR-2015

Trade Name: DUPACO BLOOD/FLUID WARMING SET
D25416
Cleared Date: 27-APR-1995

Trade Name: Dupaco Counterflo 300 Blood/Fluid Warmer
Cleared Date: 01-SEP-1995

Trade Name: DUPACO BLOOD/FLUID WARMING SET
D25416
Cleared Date: 27-APR-1995
Trade Name: imExpress - 7.2.5
Cleared Date: 29-JUL-2003
Cleared Under Data Innovations

BK060053-0  Data Innovations LLC
120 Kimball Ave., Suite 100
South Burlington, VT 05430
Trade Name: Instrument Manager - 8.05.01.10
Cleared Date: 05-JAN-2007
Cleared Under Data Innovations Inc.

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

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

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

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

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

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

BK190429-0  Delcon S.R.L
            Via Zanica
            Grassobbio, BG ITALY 24050
Trade Name: HemoMix 4 (Basic version)
            HemoMix 4 (Internal optional RFID installed version)
Cleared Date: 30-JAN-2020

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK170138-0  ETHICON Inc.
Route 22 West
P.O. Box 151
Somerville, NJ 08876
Trade Name: EVICEL™ Laparoscopic Airless Spray
Accessory (35 cm Rigid)
Cleared Date: 26-JAN-2018
BK180287-0  ETHICON Inc.
Route 22 West
P.O. Box 151
Somerville, NJ 08876
Trade Name: VISTASEAL Airless Spray Accessory
Cleared Date: 10-APR-2019

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

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

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

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

BK220719-0  EmCyte Corporation
4331 Veronica South Shoemaker Blvd
For Myers, FL 33916
Trade Name: Progenikine Concentrating System 25 M System (K191564)
Cleared Date: 07-APR-2022

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

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

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

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

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

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

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

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
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

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

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

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

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

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

Ethox Corp.
251 Seneca St,
Buffalo, NY 14204
Trade Name: Ethox Transfer Pack
Cleared Date: 17-SEP-1992
BK830010-0  Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Transfer Pack Unit(s) with Sterile Connector  
Cleared Date: 23-AUG-1988  
Cleared Under Travenol Laboratories

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

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

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

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

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

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

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

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

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

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

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

BK910032-0  Fenwal Inc
            Three Corporate Drive
            Lake Zurich, IL 60047
            Trade Name: OptiPress
            Cleared Date: 03-JUN-1993
            Cleared Under Baxter Healthcare Corporation
Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Fenwal Needle/Tube Sampling Protector/Safety Cover
Cleared Date: 12-MAR-1992
Cleared Under Baxter Healthcare Corporation

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

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

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

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

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
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

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

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

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

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

Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Sepacell R-2000 Prestorage Leukocyte Reduction Set for Red Blood Cells
Cleared Date: 14-FEB-1995
Cleared Under Baxter Healthcare Corporation
BK950013-0  Fenwal Inc
            Three Corporate Drive
            Lake Zurich, IL 60047
            Trade Name: CS-3000 Plus (mononeuclear cells)
            Cleared Date: 12-NOV-2002
            Cleared Under Baxter Healthcare Corporation

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

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

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

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

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

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

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

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

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

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

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

BK020056-0  Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: ALYX System
Cleared Date: 20-DEC-2002
Cleared Under Baxter Healthcare Corporation
BK030085-0  Fenwal Inc
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: ALYX Component Collection System and Amicus Separator System
Cleared Date: 15-MAR-2004
Cleared Under Baxter Healthcare Corporation

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

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

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

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

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

BK080024-0  Fenwal Inc
Trade Name: ALYX Component Collection System
Cleared Date: 24-JUN-2008

Trade Name: AMICUS Separator
Cleared Date: 02-OCT-2008

Trade Name: ALYX Component Collection System
Cleared Date: 22-DEC-2008

Trade Name: Bone Marrow Collection Kit and Accessories
Cleared Date: 23-JUL-2009

Trade Name: AMICUS Separator System
Cleared Date: 18-FEB-2010

Trade Name: AMICUS Separator System
Cleared Date: 04-MAR-2010

Trade Name: Autopheresis - C Plasmapheresis System
Cleared Date: 14-SEP-2017
BK100050-0  Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: Autopheresis-C Plasmapheresis system
Cleared Date: 16-NOV-2010

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

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

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

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

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

BK120082-0  Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: AMICUS Apheresis Kits
AMICUS Separator System
Cleared Date: 08-JAN-2013
BK130004-0  Fenwal Inc
Three Corporate Dr
Lake Zurich, IL 60047
Trade Name: Alyx Component Collection System
Cleared Date: 11-SEP-2013

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

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

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

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

BK080018-0  Fenwal, Inc.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: Amicus Separator System
Cleared Date: 26-AUG-2008
Cleared Under Fenwal Blood Technologies
BK080033-0  Fenwal, Inc.
Three Corporate Drive
Lake Zurich, IL 60047
Trade Name: PLASMALINK
Cleared Date: 22-AUG-2008
Cleared Under Fenwal Blood Technologies

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK870024-0  Gambro Inc.
            23872 Kelsey Road
            Barrington, IL 60010
            Trade Name: Gambro Welding Device WD2
            Cleared Date: 02-NOV-1987
BK820017-0  Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Omni-Series Control  
Cleared Date: 21-JAN-1983

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK220714-0  Genesis Biosystems Inc.
1500 Eagle Court
Lewisville, TX 75057
Trade Name: LipiVage (K172714)
Cleared Date: 05-APR-2022

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

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

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

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

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

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

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

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

BK860022-0  Genetic Testing Institute
            1701 W. Wisconsin Avenue, Suite 429
            Milwaukee, WI 53233
Trade Name: GTI-60 HLA Typing Trays
            GTI-72 HLA Typing Trays
            GTI-96 HLA Typing Trays
Cleared Date: 24-FEB-1987

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

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

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

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

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

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

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

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

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

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

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

BK960059-0  Genetic Testing Institute, Inc. (GTI)
            20925 Crossroads Circle
            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
Sutie 200
Waukesha, WI 53186
Trade Name: Lifecodes LifeScreen Deluxe
Cleared Date: 17-APR-2009

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

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

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

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

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

BK050026-0 Greiner Bio One North America, Inc.
4238 Capital Drive
Monroe, NC 28110
Trade Name: Greiner Vacuette No Additive Tubes
Cleared Date: 07-JUL-2005
BK050028-0  Greiner Bio One North America, Inc.
            4238 Capital Drive
            Monroe, NC 28110
            Trade Name: Greiner Vacuette Clot Activator Tube
            Cleared Date: 07-JUL-2005

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

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

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

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

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

BK220691-0  HUMAN MED AG
            Wilhelm-Hennemann-Strasse 9
            , Schwerin GERMANY D-19061
            Trade Name: LIPCOLLECTOR II (K101713)
            Cleared Date: 29-MAR-2022

BK200449-0  Haeleon Medical, Inc.
            1090 Lawrence Dr
Newbury Park, CA 91320
Trade Name: Healeon Duet
Cleared Date: 06-AUG-2020

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK920039-0 Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Plasma Collection System PCS2
Cleared Date: 02-SEP-1993
Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: 790 Extended Storage Platelet Collection Set
Cleared Date: 16-NOV-1993

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

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

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

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

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

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 Plalsticized PVC
            Extended Storage Platelet Bag
Cleared Date: 07-JAN-1999

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK050047-0  Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: MCS+9000, SDP revision E software, 994CF-CPP series disposable sets
Cleared Date: 21-NOV-2005
BK050048-0  Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Haemonetics MCS+ 8150 Apheresis System
Cleared Date: 27-SEP-2005

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

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

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

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

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

BK080025-0  Haemonetics Corporation
400 Wood Road
Braintree, MA 02184-9114
Trade Name: Cymbal Automated Blood Collection System
Cleared Date: 15-AUG-2008
BK090041-0  Haemonetics Corporation
            400 Wood Road
            Braintree, MA 02184-9114
            Trade Name: Symphony System
            Cleared Date: 28-SEP-2009

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

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

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

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

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

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

BK130081-0  Haemonetics Corporation
            400 Wood Road
            Braintree, MA 02184-9114
            Trade Name: Cymbal Automated Blood Collection
BK130082-0  Haemonetics Corporation
4925 Robert J Mathews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: NextGen
Cleared Date: 08-AUG-2014

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

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

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

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

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

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

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

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

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

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

BK200498-0  Haemonetics Corporation
              125 Summer St
              Boston, MA 02110
Trade Name: NexSys PCS Plasma Collection System with Persona Technology
Cleared Date: 02-OCT-2020

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

BK080038-0  Haemonetics Corporation Software Solutions
              1630 Industrial Park Street
              Covina, CA 91722-9144
Trade Name: MCS+ 9000 System
Cleared Date: 04-SEP-2008
Cleared Under Haemonetics Corporation
BK090004-0  Haemonetics Corporation Software Solutions
1630 Industrial Park Street
Covina, CA 91722-9144
Trade Name: MCS+8150 System - Wireless
Cleared Date: 20-FEB-2009
Cleared Under Haemonetics Corporation

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

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

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

BK150308-0  Haemonetics Corporation Software Solutions
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: ElDorado Donor - 3.0.0
Cleared Date: 20-NOV-2015

BK150330-0  Haemonetics Corporation Software Solutions
4925 Robert J. Matthews Parkway
Suite 100
El Dorado Hills, CA 95762
Trade Name: NextGen 3.0.0
Cleared Date: 03-MAR-2016

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

TRADE NAME: CLX TRANSFER BAG
Cleared Date: 15-AUG-1984
Cleared Under Cutter Biological

trade name: neocel system
Cleared Date: 22-MAY-1986
Cleared Under Miles, Inc.

trade name: leukotrap system
Cleared Date: 05-AUG-1986
Cleared Under Cutter Biological

trade name: cutter ppp harness
Cleared Date: 17-SEP-1986
Cleared Under Miles, Inc.

trade name: component aliquot system
Cleared Date: 07-DEC-1987
Cleared Under Miles, Inc.

trade name: blood collection unit w/o
Anticoagulant
Cleared Date: 24-JUN-1987
Cleared Under Cutter Biological

trade name: phlebotomist protection device
Cleared Date: 27-JAN-1992
Cleared Under Miles, Inc.
BK920027-0  Haemonetics Manufacturing Inc. 
   400 Wood Road 
   Braintree, MA 02184 
   Trade Name: Plasma Pooling Bag 
   Cleared Date: 13-APR-1993 
   Cleared Under Miles, Inc.

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

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

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

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

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

BK050015-0  Haemonetics Manufacturing Inc. 
   400 Wood Road 
   Braintree, MA 02184 
   Trade Name: Leukotrap SC RC Filtration System 
   Cleared Date: 14-APR-2005 
   Cleared Under MEDSEP Corp.
BK050034-0  Haemonetics Manufacturing Inc.
400 Wood Road
Braintree, MA 02184
Trade Name: Pall Acrodose PL System, Platelet Pool and Store Set with eBDS
Pall Platelet Pool and Store Set with Pall eBDS
Cleared Date: 28-SEP-2005
Cleared Under Medsep Corporation

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

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

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

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

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

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

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

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

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

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

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

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

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

BK000037-0  Harvest Technologies Corp
40 Grissom Road
Plymouth, MA 02360
Trade Name: Harvest PRP Separation System
Cleared Date: 05-FEB-2001
Cleared Under Harvest Technologies

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

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

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

BK220696-0  Harvest Technologies Corp
40 Grissom Road
Plymouth, MA 02360
Trade Name: ADIPREP ADIPOSE TRANSFER SYSTEM
(K121005)
Cleared Date: 29-MAR-2022

BK200526-0  Headspring Healthcare, Inc
10415 Morado Circle
Austin, TX 78759
Trade Name: NDDR and CDCS
Cleared Date: 18‐NOV‐2020

BK170136‐0  Healeon Medical, Inc.
1111 Rancho Conejo Blvd #204
Newbury Park, CA 91320
Trade Name: Healeon PRP Platelet Preparation System
Cleared Date: 20‐NOV‐2018

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

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

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

BK060058‐0  Healthcare‐ID, Inc.
1635 Barclay Blvd.
Buffalo Grove, IL 60089
Trade Name: Donor‐ID - 3.0
Cleared Date: 08‐FEB‐2007
Cleared Under Healthcare‐ID

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

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

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

BK150279-0  Healthcare-ID, Inc.
             1635 Barclay Blvd.
             Buffalo Grove, IL 60089
Trade Name: Donor-ID 3.2 integrated with iCASI
            App iOS
Cleared Date: 12-NOV-2015

BK160039-0  Healthcare-ID, Inc.
             1635 Barclay Blvd.
             Buffalo Grove, IL 60089
Trade Name: Donor-ID 3.2 integrated with iCASI
            App Android
Cleared Date: 29-JUL-2016

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

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

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

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

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

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

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

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

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

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

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

BK200513-0  Hemasoft Software SL
Calle Antonio Lopez, 249 4
, Madrid SPAIN 28041
Trade Name: e-Delphyn LIS Donor - 11.0.0.1
Cleared Date: 09-NOV-2020

BK200515-0  Hemasoft Software SL
Calle Antonio Lopez, 249 4
, Madrid SPAIN 28041
Trade Name: e-Delphyn Donor - 11.0.0.1
Cleared Date: 05-NOV-2020

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

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

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

BK080031-0  Hemerus Medical, LLC
5000 Township Parkway
Saint Paul, MN 55110
Trade Name: HEMERUS LEUKOSEP HRC-600-C
Leukocyte Reduction Filtration
System for Red Blood Cells
Cleared Date: 11-SEP-2008
BK120022-0  Hemo bioscience
          801 Capitola Drive, Suite 9
          Research Triangle Park
          Durham, NC 27713
          Trade Name: C3 Control Cells
          Cleared Date: 24-OCT-2012

BK140161-0  Hemo bioscience
          801 Capitola Drive, Suite 9
          Research Triangle Park
          Durham, NC 27713
          Trade Name: HemoQ QC
          Cleared Date: 08-SEP-2014

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

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

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

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

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

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

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

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

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

BK200519-0  Holding Technologies  
600-A Royal Commerce Rd  
Suite A  
Royal Palm Beach, FL 33411  
Trade Name: Maximus Blood PRP Kit  
Cleared Date: 19-NOV-2020

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

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

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

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

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

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

BK170102-0  ITL Corporation Pty, Ltd
41-45 Tennant Street
Canberra ACT 2609, AUSTRALIA
Trade Name: Samplok Segment Sampler
Cleared Date: 28-NOV-2017

BK980008-0  ITL Corporation, LTD.
22 Molonglo Mall
Fyshwick, Canberra AUSTRALIA 2609
Trade Name: Bloodpack Needle Protector (BNP)
Cleared Date: 07-APR-1998

BK820010-0  Idas America Ltd.
Lockview Plaza
Lockport, NY 14094
Trade Name: Animec
Cleared Date: 14-SEP-1982

BK130046-0  Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: LIFECODES(R) LifeScreen Deluxe (LMX)
Cleared Date: 23-SEP-2013

BK140163-0  Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: PakPlus
Cleared Date: 27-APR-2015

BK160035-0  Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: LIFECODES LifeScreen Deluxe (LMX)
Cleared Date: 21-APR-2016

BK180181-0  Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: DonorScreen-HLA Class I and Class II
Cleared Date: 14-JUN-2018

BK190439-0  Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: MATCH IT!® DNA
Cleared Date: 21-JAN-2020

BK210572-0  Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: MATCH IT!® Antibody
MATCHI IT! Antibody
Cleared Date: 19-NOV-2021

BK210573-0  Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: LIFECODES LSA Class I
LIFECODES LSA Class II
Cleared Date: 22-NOV-2021

BK210574-0  Immucor GTI Diagnostics, Inc.
20925 Crossroads Circle
Waukesha, WI 53186
Trade Name: LIFECODES LSA Class II
Cleared Date: 19-NOV-2021

BK130075-0  Immucor Transplant Diagnostics, Inc.
550 West Avenue
Stamford, CT 06902-6352
Trade Name: LIFECODES HLA-A SSO Typing Kit for use with Luminex
LIFECODES HLA-A eRES SSO Typing Kit for use with Luminex
LIFECODES HLA-B SSO Typing Kit for use with Luminex
LIFECODES HLA-B eRES SSO Typing Kit for use with Luminex
LIFECODES HLA-C eRES SSO Typing Kit for use with Luminex
LIFECODES HLA-DQB SSO Typing Kit
for use with Luminex
LIFECODES HLA-DRB1 SSO Typing Kit
for use with Luminex
LIFECODES HLA-DRB1 eRES SSO Typing Kit for use with Luminex
Cleared Date: 24-DEC-2013

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

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

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

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

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

BK830007-0  Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Low Ionic Strength Solution (LISS)
Cleared Date: 11-MAY-1983
BK830013-0  Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Rh-Hr Control
Cleared Date: 19-JUL-1983

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

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

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

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

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

BK880010-0  Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R (I and II)
Cleared Date: 03-JUN-1988
BK880011-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R (Pooled)
Cleared Date: 03-JUN-1988

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

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

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

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

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

BK890014-0 Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Capture-R Ready-Id
Cleared Date: 21-JUN-1990
BK890022-0  Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Ficin Solution Reagent Set
Cleared Date: 26-JAN-1990

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

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

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

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

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

BK960018-0  Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ABS QC Test System/ABS QC Test System Plus
Cleared Date: 21-JUL-1997
BK960019-0  Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ABS2000
Cleared Date: 30-JUN-1998

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

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

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

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

BK010020-0  Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: ABS2000 with Version 2.05.00A Software
ABS2000 with Version 2.05.00B Software
ABS2000 with Version1.00.30A SR-2 Software
Cleared Date: 24-SEP-2001

BK020053-0  Immucor, Inc.
Trade Name: Capture-R Ready Indicator Red Cells
Cleared Date: 27-JAN-2003

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

Trade Name: Monoclonal Control
Cleared Date: 23-APR-2004

Trade Name: Galileo version 1.3.6 SP4
Cleared Date: 23-APR-2004

Trade Name: Galileo QC Cell
Cleared Date: 22-APR-2004

Trade Name: DAT Positive Control Cell
Cleared Date: 23-APR-2004

Trade Name: Capture-R Select Solid Phase System
Cleared Date: 28-APR-2004
BK040057-0  Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Check cell (Weak)
Cleared Date: 06-OCT-2004

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

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

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

BK070013-0  Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: Monoclonal Control
Cleared Date: 14-JUN-2007

BK070014-0  Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: DAT Positive Control Cell
Cleared Date: 14-JUN-2007

BK070015-0  Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, GA 30091-5625
Trade Name: WB corQC  
Cleared Date: 14-JUN-2007

BK070016-0  Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Galileo Echo Automated Blood Bank System  
Cleared Date: 14-JUN-2007

BK070039-0  Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: corQC Extend  
Cleared Date: 28-SEP-2007

BK070040-0  Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Galileo Automated Blood Bank System with assays to perform red blood cell phenotyping  
Cleared Date: 28-SEP-2007

BK070051-0  Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Immucor's WB corQC  
Cleared Date: 16-NOV-2007

BK070054-0  Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Galileo with Reverse ABO Group Assay  
Cleared Date: 30-NOV-2007

BK080070-0  Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Automated Blood Bank Analyzer  
Cleared Date: 05-FEB-2009

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

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

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

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

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

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

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

BK150333-0  Immucor, Inc.
3130 Gateway Drive
BK170067-0  Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Galileo Neo
Cleared Date: 19-JUL-2017

BK170132-0  Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: Echo Lumena
Cleared Date: 27-APR-2018

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

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

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

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

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

BK200474-0  Immucor, Inc.
3130 Gateway Drive
Norcross, GA 30071
Trade Name: NEO Iris
Cleared Date: 12-JUN-2020

BK200483-0  Immucor, Inc.
            3130 Gateway Drive
            Norcross, GA 30071
Trade Name: Echo Lumena
            Galileo Echo (v.2.0)
Cleared Date: 22-JUN-2020

BK200502-0  Immucor, Inc.
            3130 Gateway Drive
            Norcross, GA 30071
Trade Name: Galileo NEO
Cleared Date: 13-OCT-2020

BK200542-0  Immucor, Inc.
            3130 Gateway Drive
            Norcross, GA 30071
Trade Name: Capture-CMV - 0066206, 0066216
Cleared Date: 08-FEB-2021

BK210560-0  Immucor, Inc.
            3130 Gateway Drive
            Norcross, GA 30071
Trade Name: Galileo NEO
            NEO Iris
Cleared Date: 12-APR-2021

BK210562-0  Immucor, Inc.
            3130 Gateway Drive
            Norcross, GA 30071
Trade Name: Galileo NEO
            NEO Iris
Cleared Date: 12-APR-2021

BK210600-0  Immucor, Inc.
            3130 Gateway Drive
            Norcross, GA 30071
Trade Name: Galileo NEO
            NEO Iris
Cleared Date: 03-SEP-2021

BK210605-0  Immucor, Inc.
            3130 Gateway Drive
            Norcross, GA 30071
Trade Name: Galileo NEO
Cleared Date: 03-SEP-2021
BK220669-0  Immucor, Inc.
            3130 Gateway Drive
            Norcross, GA 30071
            Trade Name: NEO Iris
            Cleared Date: 26-JUL-2022

BK220670-0  Immucor, Inc.
            3130 Gateway Drive
            Norcross, GA 30071
            Trade Name: Galileo NEO
            Cleared Date: 26-JUL-2022

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK050041-0  Information Data Management, Inc.
            9701 West Higgins Road
            Rosemont, IL 60018
            Trade Name: IDM Prelude System, Version 1.1
            Cleared Date: 18-JUL-2005

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

BK220700-0  Ingeneron Inc.
            8205 EL RIO
HOUSTON, TX 77054
Trade Name: SMARTGRAFT 30 SYSTEM (K141591)
Cleared Date: 29-MAR-2022

BK220701-0 Ingeneron Inc.
8205 EL RIO
HOUSTON, TX 77054
Trade Name: SMARTGRAFT 200 SYSTEM (K141713)
Cleared Date: 29-MAR-2022

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 2997 Plastic for 2991
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
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<td>Buffalo, NY 14213-1098</td>
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<td>Trade Name: Jewett Models BPL13,BPL21,BPL25</td>
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<td>Cleared Date: 08-AUG-1996</td>
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<td>Trade Name: Models BBR17, BBR25, BBR37 &amp; BBR55</td>
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<td>Trade Name: Jewett Model BPL55</td>
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<th>BK220716-0</th>
<th>Jointechlabs, Inc.</th>
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<td>108 South Wynstone Park Drive</td>
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</table>
North Barrington, IL 60010
Trade Name: Jtl-250-01 (K182732)
Cleared Date: 05-APR-2022

Jointechlabs, Inc.
108 South Wynstone Park Drive
North Barrington, IL 60010
Trade Name: KTA Adipose Treatment Kit (K190386)
Cleared Date: 07-APR-2022

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

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

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

Kawasumi Laboratories, Inc.
1900 K Street
Washington,, DC 20006
Trade Name: Kawasumi Laboratories Phlebotomy Sey
Cleared Date: 20-MAR-2000

Kawasumi Laboratories, Inc.
Shinagawa Intercity Tower B
2-15-2 Konan
Minato-Ku
Tokyo, JAPAN 108-6109
Trade Name: Kawasumi Laboratories Blood Drawing Kit (BDK) System - BK-64A
Kawasumi Laboratories Blood Drawing Kit (BDK) System
Cleared Date: 27-SEP-2017

Kaylight Corporation
602 Anacapa
Irvine, CA 92602
Trade Name: My Cells Autologous Platelet Preparation Kit
Cleared Date: 25-SEP-2009

BK200456-0  Kedrion S.p.A.
Loc. Ai Conti
Barga, Lucca ITALY 55051
Trade Name: GeTrap
Cleared Date: 20-APR-2020

BK840005-0  Kontron Blood Bank Systems
9 Plymouth Street
Everett, MA 02149
Trade Name: Kontron Microgroupamatic
Cleared Date: 27-JUN-1984

BK870012-0  Kontron Blood Bank Systems
9 Plymouth Street
Everett, MA 02149
Trade Name: LHS-500 Sampler and Delivery System
Cleared Date: 02-NOV-1987

BK890008-0  Kontron Blood Bank Systems
9 Plymouth Street
Everett, MA 02149
Trade Name: G-1000
G-2000
G-2000 MK II
Cleared Date: 30-AUG-1989

BK040053-0  Korchek Technologies, LLC
770 Plattsville Road
Trumbull, CT 06611
Trade Name: CareChek Patient Identification System, CareChek TX - version 1
Cleared Date: 12-AUG-2005

BK030037-0  Kowa Company, Ltd.
c/o Quintiles Consulting
1801 Rockville Pike, Suite 300
Rockville, MD 20852
Trade Name: LD-2000 Leukocyte Counter
Cleared Date: 14-JUN-2004

BK210558-0  LUVO Medical Technologies, Inc.
125 Fleming Dr
, Cambridge CANADA N1T 2B8
Trade Name: World PRP
Cleared Date: 23-JUL-2021
**BK100024-0**  Lab 21 Healthcare Ltd  
184 Cambridge Science Park  
Cambridge, Cambridgeshire UNITED KINGDOM CB4 0GA, UK  
Trade Name: Lab 21 TPHA OC Kit  
Cleared Date: 03-AUG-2010

**BK860031-0**  Lab-Line Instruments, Inc.  
15th and Bloomingdale Avenues  
Melrose Park, IL 60160  
Trade Name: Hema-Bath  
Cleared Date: 02-MAR-1987

**BK110055-0**  Lattice, Inc.  
1751 South Naperville Rd  
Suite 100  
Wheaton, IL 60189  
Trade Name: MediCopia Transfusion - v4.1  
Cleared Date: 06-JAN-2012

**BK860023-0**  Level 1 Technologies, Inc.  
160 Weymouth Street  
Rockland, MA 02370  
Trade Name: Level 1 Fluid Warmer  
Cleared Date: 25-SEP-1986

**BK920021-0**  Level 1 Technologies, Inc.  
160 Weymouth Street  
Rockland, MA 02370  
Trade Name: A/V Rewarming Procedural Kit Gentilello Technique  
Cleared Date: 29-JAN-1993

**BK940056-0**  Level 1 Technologies, Inc.  
160 Weymouth Street  
Rockland, MA 02370  
Trade Name: Level I Fluid Warmer  
Cleared Date: 27-DEC-1994

**BK020043-0**  Level 1 Technologies, Inc.  
160 Weymouth Street  
Rockland, MA 02370  
Trade Name: level 1 fluid warming system  
Cleared Date: 16-JUN-2003

**BK070038-0**  Life Technologies Corporation  
9099 North Deerbrook Trail  
Brown Deer, WI 53223  
Trade Name: AllSet Gold SSP  
Cleared Date: 26-SEP-2007
Cleared Under Invitrogen Corporation

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

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

BK110038-0  Life Technologies Corporation  
9099 North Deerbrook Trail  
Brown Deer, WI 53223  
Trade Name: SeCore HLA Sequencing System  
   uType Dx HLA Analysis Software v 1.0  
Cleared Date: 05-FEB-2013

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

BK220709-0  LifeCell Corporation  
One Millennium Way  
Branchburg, NJ 08876  
Trade Name: Revolve Envi 600 Advanced Adipose System (K163647)  
Cleared Date: 01-APR-2022

BK220721-0  LifeCell Corporation  
One Millennium Way  
Branchburg, NJ 08876  
Trade Name: REVOLVE ENVI 600 Advanced Adipose System (K193539)  
Cleared Date: 07-APR-2022

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

BK090064-0  LifeSouth Community Blood Centers Inc.
4039 Newberry Road
Gainesville, FL 32607
Trade Name: Integrated Blood Bank Information System
Cleared Date: 08-DEC-2009

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

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

BK220703-0  Lipogems International SpA
Viale Bianca Maria 24
Milan, Milano ITALY 20129
Trade Name: The Lipogems System (K142682)
Cleared Date: 31-MAR-2022

BK220707-0  Lipogems International SpA
Viale Bianca Maria 24
Milan, Milano ITALY 20129
Trade Name: Lipogems System (K161636)
Cleared Date: 01-APR-2022

BK220712-0  Lipogems International SpA
Viale Bianca Maria 24
Milan, Milano ITALY 20129
Trade Name: Lipogems System (K171135)
Cleared Date: 05-APR-2022

BK220685-0  Lipose Corp
2647 Lin Gate Court
Pleasanton, CA 94566
Trade Name: LIPOSE FAT TRANSFER SYSTEM (K081848)
Cleared Date: 28-MAR-2022
BK830006-0  Liquid Crystal Products, Inc.
724 Algonquin Road
Arlington Heights, IL 60005
Trade Name: HemoTemp II Blood Temperature Indicator
Cleared Date: 04-MAY-1983

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

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

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

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

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

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

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

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

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

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

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

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

BK100043-0  MEDIWARE INFORMATION SYSTEMS, INC.
             11711 West 79th Street
             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

BK160008-0  MacoProductions S.A.S.
            c/o Hoppe Regulatory Consultants
            2335 massey Lane
            Decatur, GA 30033
Trade Name: Leucolab LCG2 Leukoreduction
            System for Red Blood Cells
Cleared Date: 02-MAY-2003

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

BK080060-0  MacoProductions S.A.S.
            1733 Canton Lane
            Suite 103
            Marietta, GA 30062-2679
Trade Name: Leucolab LCG2 Leukoreduction
            System for AS-1, AS-3, and AS-5
            Red Blood Cells
Cleared Date: 14-JAN-2009

BK120071-0  MacoProductions S.A.S.
            3675 Crestwood Parkway
            Suite 260
            Duluth, GA 30096
Trade Name: Leucolab LCG2 Leukoreduction
            Systems for AS-1 Red Blood Cells
            Leucolab LCG2 Leukoreduction
            Systems for AS-1 and AS-3 Red
            Blood Cells
            Leucolab LCG2 Leukoreduction
            Systems for AS-1, AS-3 and AS-5
            Red Blood Cells
Cleared Date: 22-FEB-2013

BK160095-0  MacoProductions S.A.S.
            200 chaussee Fernand Forest
Trade Name: MacoMix HM20 and optional Hemolog 6 Software
Cleared Date: 11-AUG-2017

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

BK180306-0 MacoProductions S.A.S.
200 chaussee Fernand Forest, Tourcoing FRANCE 59200
Trade Name: MacoPress Smart Smarter and DMS Plus
Cleared Date: 24-JAN-2019

BK960075-0 Mallinckrodt Medical, Inc.
675 McDonnell Boulevard
St. Louis, MO 63134
Trade Name: Alton Dean Fluid Warmer, FW-537
Cleared Date: 28-FEB-1997

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

BK220686-0 Medi-Khan USA INC
655 North Berry St
Brea, CA 92821
Trade Name: LIPOKIT WITH DISPOSABLE 50CC AFT SYRINGE MODEL ZLK-100 (K083455)
Cleared Date: 28-MAR-2022

BK220697-0 Medi-Khan USA INC
655 North Berry St
Brea, CA 92821
Trade Name: LIPOKIT WITH DISPOSABLE 50CC AFT SYRINGE (K121703)
Cleared Date: 29-MAR-2022

BK220687-0 Medical Device Resource Corp
23392 Connecticut St
Hayward, CA 94545
Trade Name: LIPISYSTEMS AQUAVAGE MODELS AV2000 AND AV1200 (K092284)
Cleared Date: 28-MAR-2022
BK180219-0  Medical Information Technology, Inc.  
  Meditech Circle  
  Westwood, MA 02090  
  Trade Name: MEDITECH Expanse Blood Bank  
  Cleared Date: 12-SEP-2018

BK920031-0  Medical Marketing Consultants  
  3 Bethesda Metro Center,Suite 750  
  Bethesda, MD 20814  
  Trade Name: sHLA-STAT B27 ELISA for HLA-B27 Typing  
  Cleared Date: 20-AUG-1993

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

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

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

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

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

BK030078-0  Mediware Information Systems, Inc.  
  4545 Fuller Drive, Ste 320  
  Irving, TX 75038  
  Trade Name: HCLL - 2.6  
  Cleared Date: 08-APR-2004
BK040047-0  Mediware Information Systems, Inc.
        4545 Fuller Drive, Ste 320
        Irving, TX 75038
Trade Name: Instrument Interface Engine - 1.0
Cleared Date: 16-JUL-2004

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

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

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

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

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

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

BK180200-0  Mediware Information Systems, Inc.
        11711 West 79th St
        Lenexa, KS 66214
Trade Name: LifeTrak 2018
Cleared Date: 03-JUL-2018

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

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

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

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

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

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

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

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

BK220706-0  Miami Fat Supply
1510 Max Hooks Rd
Suite F
Groveland, FL 34736
Trade Name: The Red Head Collection Device The Jordy Connection System (K161372)
Cleared Date: 01-APR-2022

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

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

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

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

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

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

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

Micro Typing Systems Inc.
1295 S.W. 29th Ave.
Pompano Beach, FL 33069
<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Date of Clearance</th>
<th>Company Details</th>
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<tbody>
<tr>
<td>MTS™ Buffered Gel Card</td>
<td>08-JUL-2019</td>
<td>Micro Typing Systems Inc. 1295 S.W. 29th Ave. Pompano Beach, FL 33069</td>
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<tr>
<td>MTS™ Buffer Gel Card</td>
<td>17-DEC-2019</td>
<td>MicroAire Surgical Instruments, LLC. 3590 Grand Forks Boulevard Charlottesville, VA 22911</td>
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<tr>
<td>MicroAire LipoFilter® System</td>
<td>16-MAR-2022</td>
<td>MicroAire Surgical Instruments, LLC. 3590 Grand Forks Boulevard Charlottesville, VA 22911</td>
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<td>LipoFilter - Hospital Pack</td>
<td>31-MAR-2022</td>
<td>MicroAire Surgical Instruments, LLC. 3590 Grand Forks Boulevard Charlottesville, VA 22911</td>
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<td>LipoFilter - Clinic Pack (K150779)</td>
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<td>Leukocyte Typing Serum Trays</td>
<td>12-OCT-1984</td>
<td>Micronics 8463 154th Avenue NE Redmond, WA 98052</td>
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<td>Lambda Cell Tray</td>
<td>20-NOV-1984</td>
<td>Micronics 8463 154th Avenue NE Redmond, WA 98052</td>
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<td>ABORhCard</td>
<td>30-APR-2010</td>
<td>Microwave Medical System 310-312 School St. Acton, MA 01720</td>
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<td>QWIK-1 Bld. and Plasma Warmer</td>
<td>29-JUL-1993</td>
<td>Microwave Medical System 310-312 School St. Acton, MA 01720</td>
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<td>Qwik - 1 TM - 500</td>
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Cleared Date: 24-FEB-1994

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

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

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

BK220726-0 Millennium Medical Technologies Inc (DBA Cellmyx)
6352 Corte Del Abeto Ste A
Carlsbad, CA 92011
Trade Name: IntelliFat Disposable Adipose Tissue Harvesting and Transfer Kit, IntelliFat Body On Demand (BOD) Kit (K210528)
Cleared Date: 12-APR-2022

BK220711-0 Millennium Medical Technologies, INC
460 Saint Michaels Drive
Suite 901
Santa FE, NM 87505
Trade Name: Autoclavable Suction Jar with Luer Lock extension - 250 500 1000 2000 and 3000 ml (K170449)
Autoclavable Suction Jar without Luer Lock extension - 1500 and 2500 ml Sterile 1500 and 2500 (K170449)
Lids with Conical patient connection 6-10 and overflow protection (K170449)
Cleared Date: 05-APR-2022

BK210653-0 Millipore (UK) Ltd
Fleming Road, Kirkton Campus
Livingston UNITED KINGDOM EH54 7BN
Trade Name: ORTHO Daily QC, Simulated Whole
Blood Quality Control Kit (ORTHODaily QC Kit)
Cleared Date: 07-JUN-2022

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

BK030065-0  Mississippi Blood Services, Inc.
            1995 Lakeland Drive
            Jackson, MS 39216
Trade Name: WebLab Online Laboratory System - 2.0
Cleared Date: 22-DEC-2003

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

BK940044-0  Mona Barres
            516 Sean Dr.
            Metairie, LA 70005
Trade Name: VacMatic Ihs 3-15
Cleared Date: 07-SEP-1994

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

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

BK910016-0  NPBI
            Runde ZZ 41, 7881 HM Emmer Compascuum
            Emmer-Compascum, NETHERLANDS
Trade Name: Compomat
Cleared Date: 30-MAR-1992
BK930018-0  NPBI
  Runde ZZ 41, 7881 HM Emmer Compascuum
  Emmer-Compascumm, NETHERLANDS
  Trade Name: Blood Collection Mixer MW 5001
  Cleared Date: 24-JUL-1994

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

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

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

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

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

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

BK120068-0  Nanoentek, Inc.
  300 Washington St., STE 416
  Newton, MA 02458
  Trade Name: ADAM-rWBC
  Cleared Date: 05-DEC-2012
BK180283-0 Nanoentek, Inc.
12f, 5, Digital-Ro 26-Gil Guro-Gu,
Seoul KOREA, SOUTH 152-740
Trade Name: ADAMII CD34 System
Cleared Date: 09-AUG-2019

BK200525-0 Nanoentek, Inc.
851 14, Seohae ro, Paltan myeon
Hwaseong si,
Gyeonggido KOREA, SOUTH 18521
Trade Name: ADAM-rWBC HT System
ADAM-rWBC HT System with ADAM-rWBC Kit
Cleared Date: 01-DEC-2020

BK210621-0 Nanoentek, Inc.
NanOEntek, Inc.
851-14 Seohae-ro, Paltan-myeon
Hwaseong-si KOREA, SOUTH 18531
Trade Name: r-Control RBC and PLT
Cleared Date: 28-OCT-2021

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

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

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

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

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

BK180301-0  Newmarket Biomedical Ltd
              Unit 1 Lanwades Business Park
              , Kentford UNITED KINGDOM CB8 7PN
Trade Name: PK7400 TP HA Controls
PK7400 TP HA Reagent
Cleared Date: 01-AUG-2019

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK930024-0  Olympus Corporation
4 Nevada Drive
Lake Success, NY 11042
Trade Name: Olympus PK7200 Blood Grouping Analyzer
Cleared Date: 26-JAN-1994
BK140093-0  Omrix Biopharmaceuticals Ltd.
PO Box 151, Route22 West
Somerville, NJ 08876-0151
Trade Name: Evicel Application Device
Cleared Date: 03-SEP-2014

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK200546-0 One Lambda, Inc.
22801 Roscoe Blvd
West Hills, CA 92304
Trade Name: LABScreen Multi
Cleared Date: 12-JAN-2021

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BK120006-0  Ortho-Clinical Diagnostics, Inc.
1001 U.S. Highway 202
Raritan, NJ 08869-0606
Trade Name: ORTHO VERSEIA Pipetter as Part of
the ORTHO Summit System (OSS) v
3.0
Cleared Date: 15-MAR-2012

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

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

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

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

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

BK190399-0  Ortho-Clinical Diagnostics, Inc.
            1001 U.S. Highway 202
            Raritan, NJ 08869-0606
            Trade Name: ORTHO VISION Max Analyzer
Cleared Date: 17-DEC-2019

BK200549-0  Ortho-Clinical Diagnostics, Inc.
            1001 U.S. Highway 202
            Raritan, NJ 08869-0606
            Trade Name: ORTHO Optix™ Reader
Cleared Date: 10-MAR-2021

BK210557-0  Ortho-Clinical Diagnostics, Inc.
            1001 U.S. Highway 202
            Raritan, NJ 08869-0606
            Trade Name: ORTHO VISION® Analyzer
            ORTHO VISION® Max Analyzer
Cleared Date: 13‐MAY‐2021

BK210564-0  Ortho‐Clinical Diagnostics, Inc.
            1001 U.S. Highway 202
            Raritan, NJ 08869‐0606
            Trade Name: ORTHO VISION® Analyzer
            ORTHO VISION® Max Analyzer
            Cleared Date: 13‐MAY‐2021

BK220724-0  Ortho‐Clinical Diagnostics, Inc.
            1001 U.S. Highway 202
            Raritan, NJ 08869‐0606
            Trade Name: ORTHO Optix™ Reader
            Cleared Date: 24‐JUN‐2022

BK040017-0  Orthogen Therapeutics, GmbH
            Graf‐Adolf‐Str. 43
            D‐40210 Dusseldorf, GERMANY
            Trade Name: Osteokin System
            Cleared Date: 23‐JUN‐2004

BK080014-0  Pall Corporation
            25 Harbor Park Drive
            Port Washington, NY 11050‐4630
            Trade Name: Pall eBDS
            Cleared Date: 13‐FEB‐2009
            Cleared Under Pall Life Sciences

BK150314-0  Pall Corporation
            25 Harbor Park Drive
            Port Washington, NY 11050‐4630
            Trade Name: Pall? Briostor? Transfer/Freezing
            Bag Set
            Cleared Date: 16‐JUN‐2016

BK120029-0  PatientSafe Solutions
            5375 Mira Sorrento Place
            Suite 500
            San Diego, CA 92121
            Trade Name: Patient Touch(TM) Blood Product
            Administration System v3.2.1
            Cleared Date: 13‐NOV‐2012

BK820002-0  Pel‐Freez Clinical Systems, LLC
            PO Box 68
            Rogers, AR 72756
            Trade Name: Not available from BLT migrated
            data.
            Cleared Date: 06‐OCT‐1982
BK820023-0  Pel-Freez Clinical Systems, LLC
PO Box 68
Rogers, AR 72756
Trade Name: Leukocyte Typing Serum (Human)
(Tray Package)
Cleared Date: 12-JAN-1983

BK850004-0  Pel-Freez Clinical Systems, LLC
9099 N. Deerbrook Trail
Brown Deer, WI 53223
Trade Name: Frozen Leukocyte Panel (Human)
Cleared Date: 01-AUG-1985

BK000019-0  Pel-Freez Clinical Systems, LLC
9099 N. Deerbrook Trail
Brown Deer, WI 53223
Trade Name: UniTray SSP HLA Typing Kits
Cleared Date: 29-JAN-2001

BK020068-0  Pel-Freez Clinical Systems, LLC
9099 N. Deerbrook Trail
Brown Deer, WI 53223
Trade Name: Pel Freez HLA High Resolution SSP
UniTray
Cleared Date: 14-JAN-2003

BK030003-0  Pel-Freez Clinical Systems, LLC
9099 N. Deerbrook Trail
Brown Deer, WI 53223
Trade Name: UniMatch Plus
Cleared Date: 25-FEB-2003

BK050055-0  Perfusion Partners & Associates, Inc.
6227 Foxfire Lane
Fort Myers, FL 33912
Trade Name: GenesisCS Component Concentrating System
Cleared Date: 13-OCT-2006

BK900018-0  Polar Products, Inc.
2808 Oregon Ct. Bldg K-4
Torrance, CA 90503
Trade Name: Polar Products' Model MTE-58L
Cleared Date: 30-AUG-1990

BK060056-0  Prescott Ideas LLC
8960 E. Anna Place
Tucson, AZ 85710
Trade Name: Antibody Check - 4.1
Cleared Date: 23-APR-2007
BK140119-0  ProFibrix BV
            Darwinweg 24
            Leiden, NETHERLANDS
            Trade Name: RaplixaSpray Device
            Cleared Date: 30-APR-2015

BK170092-0  Progenika Biopharma, S.A.
            Ibaizabal bidea, Edificio 504
            Parque Tecnologico de Bizkaia
            Derio, Bizkaia,
            Trade Name: ID CORE CONTROL
            Cleared Date: 11-OCT-2018

BK010017-0  Psyche Systems Corp
            Ten Laurel Avenue
            Wellesley, MA 02481
            Trade Name: System Blood Bank (SBB) Software - 3.0
            Cleared Date: 04-SEP-2001

BK220720-0  Puregraft LLC
            420 Stevens Ave
            Suite 220
            Solana Beach, CA 92075
            Trade Name: Dermapose Refresh (K193363)
            Cleared Date: 07-APR-2022

BK180188-0  PuriBlood Medical Co. Ltd.
            2F., No.11, Gongye E. 9th Rd.
            Paoshan Hsiang
            , Hsinchu Hsien TAIWAN 30075
            Trade Name: Leukocyte Reduction Filter for Red Blood Cells
            Leukocyte reduction filter for red blood cells
            Cleared Date: 23-NOV-2018

BK840020-0  Queue Systems
            22 Airport Industrial Park Rd., Box 1901
            Parkersburg, WV 26102
            Trade Name: Cryostar
            Cleared Date: 23-OCT-1984

BK990005-0  R & D Systems, Inc
            614 McKinley Place N.E.
            Minneapolis, MN 55413
            Trade Name: StatusFlow Pro
            Cleared Date: 21-JUN-1999
BK000035-0  R & D Systems, Inc
614 McKinley Place N.E.
Minneapolis, MN 55413
Trade Name: R & D Leuko-Reduced RBC Control
Cleared Date: 13-DEC-2000

BK000036-0  R & D Systems, Inc
614 McKinley Place N.E.
Minneapolis, MN 55413
Trade Name: R & D Leuko-Reduced Plt Control
Cleared Date: 13-DEC-2000

BK040012-0  R & D Systems, Inc
614 McKinley Place N.E.
Minneapolis, MN 55413
Trade Name: R&D Donor Checker Hematology Control
Cleared Date: 05-MAR-2004

BK040063-0  R & D Systems, Inc
614 McKinley Place N.E.
Minneapolis, MN 55413
Trade Name: R & D Plasma Hemoglobin Hematology Control
Cleared Date: 17-SEP-2004

BK910012-0  ROCHE BIOMEDICAL LABORATORIES, INC.
112 ORANGE DRIVE
ELON COLLEGE, NC 27244
Trade Name: HLA CLASS I PHENOTYPING TRAYS
Cleared Date: 06-JAN-1992

BK200543-0  Ranfac Corporation
30 Doherty St
Avon, MA 02322
Trade Name: Ranfac Autologous Platelet Separator
Cleared Date: 24-FEB-2021

BK220704-0  Ranfac Corporation
30 Doherty St
Avon, MA 02322
Trade Name: Ranfac Fat Aspiration Transfer Syringe (FATS) Procedure Pack
Ranfac Fat Aspiration Transfer Syringe (FATS) Containment Vessel (K150156)
Cleared Date: 31-MAR-2022

BK220708-0  Ranfac Corporation
30 Doherty St
Avon, MA 02322

Trade Name: Ranfac Fat Aspiration Cannula
(K162932)
Cleared Date: 01-APR-2022

BK860034-0  Reagent Laboratory, Inc.
300 East Ottawa Avenue
Louisville, KY 40209
Trade Name: Sodium Chloride 1.3%
Cleared Date: 01-JUN-1987

BK140211-0  Reapplix Aps
Blokken 45
Birkerod, DENMARK
Trade Name: 3C Patch System
Cleared Date: 24-FEB-2016

BK170002-0  Reapplix Aps
Blokken 45
Birkerod, DENMARK
Trade Name: 3C Patch System
Cleared Date: 04-APR-2017

BK200471-0  Reapplix Aps
Blokken 45
Birkerod, DENMARK
Trade Name: 3C Patch System
Cleared Date: 13-JAN-2021

BK170095-0  RedDress Ltd
Shkedim Street 11
Pardes Hanna, ISRAEL 370110
Trade Name: RD1 System
Cleared Date: 14-JUN-2018

BK190349-0  RedDress Ltd
Shkedim Street 11
Pardes Hanna, ISRAEL 370110
Trade Name: RD2 System
Cleared Date: 08-NOV-2019

BK200464-0  RedDress Ltd
Shkedim Street 11
Pardes Hanna, ISRAEL 370110
Trade Name: RD2 System
Cleared Date: 20-MAR-2020

BK210570-0  RedDress Ltd
Shkedim Street 11
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<th>Trade Name</th>
<th>Date</th>
<th>Company Name</th>
<th>Address</th>
<th>City, Province</th>
<th>Country</th>
<th>Trade Name</th>
<th>Date</th>
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<td>RD2 Ver.02 System</td>
<td>22-JUN-2021</td>
<td>RegenLab SA</td>
<td>3428 Avenue Marcil</td>
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<td>Reichert Inc.</td>
<td>3362 Walden Ave</td>
<td>Suite 100</td>
<td>Depew</td>
<td>TS Meter-DSP</td>
<td>19-DEC-2017</td>
<td>Revco/Lindberg</td>
<td>275 Aiken Road</td>
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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

BK140195-0  Roche Molecular Systems, Inc.
4300 Hacienda Drive
P.O. Box 9002
Pleasanton, CA 94588-0900
Trade Name: Cobas p 680 Instrument
Cobas (R) 8800 System
Cleared Date: 20-OCT-2016

BK140196-0  Roche Molecular Systems, Inc.
4300 Hacienda Drive
P.O. Box 9002
Pleasanton, CA 94588-0900
Trade Name: cobas p 680 Instrument
cobas (R) 6800 System
Cleared Date: 20-OCT-2016

BK110045-0  Rowny Systems, Inc.
7555 Spring Lake Drive
Bethesda, MD 20817-6507
Trade Name: Antigen PLUS - 7.4
Cleared Date: 25-MAY-2012

BK210563-0  Royal Biologics Inc
401 Hackensack Ave
Hackensack, NJ 07601
Trade Name: Royal Maxx Autologous PRP Concentration System
Cleared Date: 16-APR-2021

BK210632-0  Royal Biologics Inc
401 Hackensack Ave
Hackensack, NJ 07601
Trade Name: Royal MAXX BMC Concentration System
Royal MAXX PRP Concentration System
Cleared Date: 11-FEB-2022

BK180204-0  Royal Biologics LLC
190 Columbus Drive
Suite #2A
Jersey City, NJ 07302
Trade Name: Royal MaxxPRP Concentration System
Cleared Date: 12-JUL-2018
BK990008-0  Rubin & Poor, Inc.
155 Maplewood Avenue #5
Maplewood, NJ 07040
Trade Name: Rubin & Poor Configurable Manual
Blot System - 1.0C
Cleared Date: 29-OCT-1999

BK000030-0  Rubin & Poor, Inc.
155 Maplewood Avenue #5
Maplewood, NJ 07040
Trade Name: Configurable Laboratory Result Manager (CLRM) - 1.0E
Cleared Date: 23-NOV-2001

BK030073-0  Rubin & Poor, Inc.
155 Maplewood Avenue #5
Maplewood, NJ 07040
Trade Name: Configurable Manual Batch Entry - 1.1A
Cleared Date: 14-JAN-2004

BK080028-0  Rubin & Poor, Inc.
155 Maplewood Avenue #5
Maplewood, NJ 07040
Trade Name: Pool results Manager
Cleared Date: 03-SEP-2008

BK050045-0  SCC Soft Computer
34350 U.S. Highway 19 North
Palm Harbor, FL 34684
Trade Name: SoftDonor 4.3 with SoftScape
Cleared Date: 26-OCT-2005

BK060059-0  SCC Soft Computer
34350 U.S. Highway 19 North
Palm Harbor, FL 34684
Trade Name: SoftDonor 4.4 with DMSI - 4.4
Cleared Date: 21-DEC-2006

BK080020-0  SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftBank II - v23.2
Cleared Date: 12-AUG-2008

BK080069-0  SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftDonor 4.5 - 4.5
Cleared Date: 16-JAN-2009
BK090017-0  SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftBank II Version 25 - 25
Cleared Date: 23-JUN-2009

BK090078-0  SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftID.Tx Version 1.0
Cleared Date: 28-APR-2010

BK100045-0  SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftBank II - 25.1
Cleared Date: 29-JUL-2010

BK140128-0  SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftBank Version 25.5
Cleared Date: 05-AUG-2014

BK200531-0  SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftBank - 25.6.1.0
    SoftBank.web - 25.6.1.0
Cleared Date: 18-DEC-2020

BK210607-0  SCC Soft Computer
5400 Tech Data Drive
Clearwater, FL 33760
Trade Name: SoftDonor Version 4.5.5.0 - 4.5.5.0
Cleared Date: 14-SEP-2021

BK950057-0  SG Scientific
5745 SW 75th Street
#284
Gainseville, FL 32608
Trade Name: The Saber (Segment Piercing Device)
Cleared Date: 13-NOV-1995

BK090047-0  SPINESMITH PARTNERS LP
93 Red River
Austin, TX 78701
Trade Name: Fusionary Graft Delivery System
Cleared Date: 10-FEB-2010

BK050052-0  STEMCO Biomedical, Inc.
2810 Meridan Parkway
Suite 148
Durham, NC 27713
Trade Name: Aldecount Progenitor Cell Enumeration Kit
Cleared Date: 02-DEC-2005

BK130052-0  STRATEC Biomedical UK Limited
1 Barberry Court, Callister Way
Burton upon Trent
Trade Name: Procleix NAT Manager Software (Version 1.1)
Cleared Date: 17-APR-2014

BK160071-0  STRATEC Biomedical UK Limited
Third Ave, Centrum 100
Burton upon Trent
Straffordshire, DE14 2WD UNITED KINGDOM
Trade Name: Aurora Enterprise - Cat. No. AUR-ENT-001
Cleared Date: 30-OCT-2017

BK160113-0  STRATEC Biomedical UK Limited
98 Main Street
Suite 205
Southington, CT 06489
Trade Name: cobas Synergy Software (Version 1.0)
Cleared Date: 19-APR-2017

BK160124-0  STRATEC Biomedical UK Limited
Third Ave, Centrum 100
Burton upon Trent
Straffordshire, DE14 2WD UNITED KINGDOM
Trade Name: ORTHO CONNECT
Cleared Date: 17-OCT-2017

BK160125-0  STRATEC Biomedical UK Limited
Third Ave, Centrum 100
Burton upon Trent
Straffordshire, DE14 2WD UNITED KINGDOM
Trade Name: Procleix? NAT Manager? v1.2 Software - v1.2
Cleared Date: 25-APR-2017
BK190434-0  STRATEC Biomedical UK Limited
Third Ave, Centrum 100
Burton upon Trent
Straffordshire, DE14 2WD UNITED KINGDOM
Trade Name: ORTHO CONNECT™ - 3.0
          Ortho Connect - 3.0
Cleared Date: 10-MAR-2020

BK940017-0  SangStat Medical Corporation
6300 Dumbarton Circle
Freemont, CA 94555
Trade Name: PRA-STAT Elisa/Panel React
Anti-HLA Class I IgG Antibody
Cleared Date: 27-SEP-1994

BK950009-0  SangStat Medical Corporation
6300 Dumbarton Circle
Freemont, CA 94555
Trade Name: CROSS STAT
Cleared Date: 09-MAY-1995

BK970019-0  SangStat Medical Corporation
6300 Dumbarton Circle
Freemont, CA 94555
Cleared Date: 30-JUL-1997

BK970037-0  SangStat Medical Corporation
6300 Dumbarton Circle
Freemont, CA 94555
Trade Name: PRA-STAT Anti-HLA CLASS I IgG
          Antibodies/Two Patients per Plate
          Format
Cleared Date: 18-NOV-1998

BK940011-0  Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name: Sanguin Medusa 2000
Cleared Date: 29-SEP-1994

BK960065-0  Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name: Sanguin Medusa 2000 - 3.4
Cleared Date: 17-DEC-1998

BK980003-0  Sanguin International
1020 Sherman Avenue
Hamden, CT 06514
Trade Name: Aurora/Fenestra (version 1.0)
Cleared Date: 29-SEP-1999

BK980039-0  Sanguin International
            1020 Sherman Avenue
            Hamden, CT 06514
Trade Name: Medusa 2000 Simport, Version 1.2
Cleared Date: 11-JUN-1999

BK090061-0  Sanguin International
            1020 Sherman Avenue
            Hamden, CT 06514
Trade Name: Sanguin Aurora version 2.0
Cleared Date: 22-DEC-2009

BK100030-0  Sanguin International
            1020 Sherman Avenue
            Hamden, CT 06514
Trade Name: Sanguin Liberty SRIMPORT - 3.1
Cleared Date: 08-JUL-2010

BK010042-0  Sarstedt, Inc.
            1025 Saint James Church Rd.
            Newton, NC 20865
Trade Name: Transwaag KL
Cleared Date: 12-DEC-2001

BK010045-0  Sarstedt, Inc.
            1025 Saint James Church Rd.
            Newton, NC 20865
Trade Name: Sahara Blood & Plasma Warming Device
Cleared Date: 21-DEC-2001

BK030006-0  Sarstedt, Inc.
            1025 Saint James Church Rd.
            Newton, NC 20865
Trade Name: Transwaag Disk 01
Cleared Date: 27-FEB-2003

BK040080-0  Sarstedt, Inc.
            1025 Saint James Church Rd.
            Newton, NC 20865
Trade Name: Sahara-TSC
Cleared Date: 09-FEB-2005

BK070029-0  Sarstedt, Inc.
            1025 Saint James Church Rd.
            Newton, NC 20865
Trade Name: S-Monovette ACD-A
Cleared Date: 21-SEP-2007

BK870028-0  Saturn BioTech Corporation
            P.O. Box 3823
            Littleton, CO 80161
            Trade Name: RMED Finger Heme Trap
            Cleared Date: 01-FEB-1988

BK940029-0  Scimed Life Systems, Inc.
            6655 Wedgewood Rd.
            Maple Grove, MN 55311
            Trade Name: SCIMED UltraFuse Coron.
                         Infusion/Guidewire Exchange
                         Catheter
            Cleared Date: 15-MAR-1995

BK870011-0  Seabrook Medical Systems, Inc.
            673 Wilmer Avenune
            Cincinnati, OH 45226
            Trade Name: ECMO-TEMP
            Cleared Date: 14-SEP-1987

BK820005-0  Separation Science Corporation
            169 Avon Street, P.O. Box 643
            Stratford, CT 06497
            Trade Name: SEPCOR Cell Line Monitor
            Cleared Date: 06-JUL-1982

BK880005-0  Separation Science Corporation
            169 Avon Street, P.O. Box 643
            Stratford, CT 06497
            Trade Name: Blood Bank Saline, Preserved
            Cleared Date: 09-JUN-1988

BK050056-0  Separation Technology, Inc.
            1096 Rainier Drive
            Altamonte Springs, FL 32714-3855
            Trade Name: UltraChek Reference Controls -
                         Product Code GLK
                         UltraCritTM Hematocrit Measurement
                         Device - Product Code GKF
            Cleared Date: 12-DEC-2005

BK960036-0  Shared Medical Systems
            51 Valley Stream Parkway
            Malvern, PA 19355
            Trade Name: SMS BB Transfusion System
            Cleared Date: 12-DEC-1997

BK220688-0  Shippert Medical Technologies Corp.
6248 South Troy Circle
Centennial, CO 80111
Trade Name: TISSU TRANS FILTRON MODELS
   3-TT-FILTRON 2000-500 (K092482)
Cleared Date: 29-MAR-2022

BK220692-0  Shippert Medical Technologies Corp.
6248 South Troy Circle
Centennial, CO 80111
Trade Name: TISSU TRANS FILTRON SYRINGE FILL
   (K102117)
Cleared Date: 29-MAR-2022

BK990018-0  Shotwell & Carr, Inc.
3535 Firewheel Drive
Suite A
Flower Mound, TX 75028-2628
Trade Name: Hot Shot Fluid Warmer Model 100
   Hot Shot Fluid Warmer Model 101
   Hot Shot Fluid Warmer Model 102
   Hot Shot Fluid Warmer Model 103
Cleared Date: 13-OCT-1999

BK090077-0  Siemens Healthcare Diagnostics, Inc.
P.O. Box 2466
Berkeley, CA 94702
Trade Name: TRUGENE HIV-1 Genotyping Kit and
   OpenGene DNA Sequencing System
Cleared Date: 28-DEC-2009
Cleared Under Siemens Healthcare Diagnostics Inc.

BK110007-0  Siemens Healthcare Diagnostics, Inc.
P.O. Box 2466
Berkeley, CA 94702
Trade Name: TRUGENE HIV-1 Genotyping Kit and
   OpenGene DNA Sequencing System
Cleared Date: 04-MAR-2011
Cleared Under Siemens Healthcare Diagnostics Inc.

BK120013-0  Siemens Healthcare Diagnostics, Inc.
P.O. Box 2466
Berkeley, CA 94702
Trade Name: TRUGENE HIV-1 Genotyping Kit and
   OpenGene DNA Sequencing System
Cleared Date: 27-MAR-2012
Cleared Under Siemens Healthcare Diagnostics Inc.

BK140152-0  Siemens Healthcare Diagnostics, Inc.
511 Benedict Ave
Tarrytown, NY 10591
Trade Name: ADVIA Centaur System (Software Version 4.0 with SP4)
Cleared Date: 08-JUN-2015

BK140153-0  Siemens Healthcare Diagnostics, Inc.
            511 Benedict Ave
            Tarrytown, NY 10591
Trade Name: ADVIA Centaur XP System (SW v 7.1)
Cleared Date: 08-JUN-2015

BK960051-0  Siemens Medical Solutions Diagnostics
            800 Dwight Way
            Berkeley, CA 94701-1986
Trade Name: PPIS - Version 2.0
Cleared Date: 07-AUG-1998
Cleared Under Bayer Corporation

BK990024-0  Siemens Medical Solutions Diagnostics
            800 Dwight Way
            Berkeley, CA 94701-1986
Trade Name: Plasma Procurement Information System (PPIS) - 3.0
Cleared Date: 03-NOV-1999
Cleared Under Bayer Corporation

BK990037-0  Siemens Medical Solutions Diagnostics
            800 Dwight Way
            Berkeley, CA 94701-1986
Trade Name: Plasma Procurement Information System (PPIS) - Version 4.0
Cleared Date: 17-NOV-1999
Cleared Under Bayer Corporation

BK060015-0  Siemens Medical Solutions Diagnostics
            P.O. Box 2466
            Berkeley, CA 94702-0466
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 21-MAR-2006
Cleared Under Bayer Healthcare Diagnostics Division

BK070009-0  Siemens Medical Solutions Diagnostics
            P.O. Box 2466
            Berkeley, CA 94702-0466
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 19-MAR-2007

BK080036-0  Siemens Medical Solutions Diagnostics
            P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 20-OCT-2008

BK080073-0  Siemens Medical Solutions Diagnostics
P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 15-JAN-2009

BK060004-0  Smith & Nephew
1450 Brooks Road
Memphis, TN 38116
Trade Name: Promote Platelet Rich Concentrate (PRC) Preparation System
Cleared Date: 02-MAY-2006

BK850011-0  Smithkline Beckman Corp.
999 West Valley Road
Wayne, PA 19087
Trade Name: Accugenics (Tray)
Cleared Date: 07-AUG-1985

BK850012-0  Smithkline Beckman Corp.
999 West Valley Road
Wayne, PA 19087
Trade Name: Accugenics (HLA Control Cells)
Cleared Date: 07-AUG-1985

BK080047-0  SofTov Ltd
32 HaShacham Street
Petach Tikva, ISRAEL 49170
Trade Name: AutoFusion - v3.02
Cleared Date: 05-JUN-2009

BK960033-0  Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name: SoftBank II Version 19.1
Cleared Date: 10-JUL-1998

BK000040-0  Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.
Palm Harbor, FL 34684
Trade Name: SoftBank II - 21.2
Cleared Date: 20-APR-2001

BK020006-0  Soft Computer Consultants Inc.
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftDonor - 4.1  
Cleared Date: 27-FEB-2003

BK020021-0  Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftBank II - 22  
Cleared Date: 11-SEP-2002

BK030018-0  Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftBank II - 23  
Cleared Date: 17-APR-2003

BK040028-0  Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftBank II with SoftScape - 23  
Cleared Date: 07-MAY-2004

BK040048-0  Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftBank II with Database Management System Interface (DMSI) - v23.1  
Cleared Date: 23-AUG-2004

BK970032-0  Sorvall, Inc.  
31 Pecks Lane  
Newtown, CT 06470  
Trade Name: RC12BP  
Cleared Date: 05-DEC-1997

BK220694-0  Sound Surgical Technologies Inc.  
357 McCaslin Boulevard  
Louisville, CO 80027  
Trade Name: ORIGINS LIPOHARVESTING SYSTEM (K120328)  
Cleared Date: 29-MAR-2022

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

BK200477-0  Suneva Medical, Inc.
             5870 Pacific Center Blvd
             San Diego, CA 92121
             Trade Name: Amplifine Gel Separator Tubes
             Suneva HD PRP Platelet Preparation
             System
             Cleared Date: 30-SEP-2020
BK990002-0  Sunquest Information Systems, Inc.
4801 Broadway Boulevard
Tucson, AZ 85711
Trade Name: Flexilab - 5.2
Cleared Date: 16-AUG-1999

BK990034-0  Sunquest Information Systems, Inc.
4801 Broadway Boulevard
Tucson, AZ 85711
Trade Name: FlexiLab Blood Bank and Blood Donor System - Version 5.2
Cleared Date: 17-NOV-1999

BK080021-0  Sunquest Information Systems, Inc.
250 S. Williams Blvd.
Tucson, AZ 85711
Trade Name: Sunquest Transfusion Manager - v1.0
Cleared Date: 14-SEP-2017

BK080042-0  Sunquest Information Systems, Inc.
250 S. Williams Blvd.
Tucson, AZ 85711
Trade Name: Sunquest Blood Bank Donor - 6.4
Cleared Date: 03-MAR-2009

BK140124-0  Sunquest Information Systems, Inc.
250 S. Williams Blvd.
Tucson, AZ 85711
Trade Name: Sunquest Transfusion Manager version 2.0
Cleared Date: 18-JUN-2014

BK160005-0  Sunquest Information Systems, Inc.
250 S. Williams Blvd.
Tucson, AZ 85711
Trade Name: Sunquest Blood Bank and Blood Donor - Version 8.0
Cleared Date: 25-MAR-2016

BK210556-0  Sunquest Information Systems, Inc.
3330 East Sunrise Dr
Tucson, AZ 85718
Trade Name: Sunquest Transfusion Manager - 3.0
Sunquest Transfusion Manager Version 3.0
Cleared Date: 16-APR-2021

BK120061-0  SynGen, Inc
2125 19th Street, Suite 120
Sacramento, CA 95818
Trade Name: SynGenX-1000
Cleared Date: 12-JUL-2013

BK220723-0  Syntr Health Technologies, Inc.
            5270 California Ave
            Irvine, CA 92617
Trade Name: Syntrfuge System (K203800)
Cleared Date: 07-APR-2022

BK120067-0  SysLogic, Inc.
            375 Bishops Way, Suite 105
            Brookfield, WI 53005
Trade Name: iTrace for Blood Centers - 1.0.924.0
Cleared Date: 14-SEP-2017

BK960034-0  SysTec Computer Associates, Inc.
            738 Smithtown Bypass
            Smithtown, NY 11787
Trade Name: Lifetec Comm. Blood Center System-Rev 2.10
Cleared Date: 28-JUL-1998

BK990003-0  SysTec Computer Associates, Inc.
            28 North Country Road
            Mt. Sinai, NY 11766
Trade Name: LifeTec - 2.20
Cleared Date: 30-JUL-1999

BK040026-0  SysTec Computer Associates, Inc.
            28 North Country Road
            Mt. Sinai, NY 11766
Trade Name: LifeTec Donor Verification and Collection System (DOVAC) - 1.00
Cleared Date: 21-OCT-2004

BK060032-0  SysTec Computer Associates, Inc.
            28 North Country Road
            Mt. Sinai, NY 11766
Trade Name: LifeTec Elite - 1.0
Cleared Date: 15-AUG-2006

BK210559-0  Sysmex America, Inc.
            577 Aptakisic Rd
            Lincolnshire, IL 60069
Trade Name: Sysmex XN-10 Automated Hematology Analyzer
Cleared Date: 27-MAY-2021
BK210631-0  Sysmex America, Inc.
             577 Aptakisic Rd
             Lincolnshire, IL 60069
Trade Name: Sysmex XN-10 Automated Hematology
            Analyzer
Cleared Date: 23-MAY-2022

BK120076-0  TERUMO BCT
             10811 W. Collins Ave
             Lakewood, CO 80215-4440
Trade Name: Spectra Optia Apheresis System
Cleared Date: 25-FEB-2013

BK130031-0  TERUMO BCT
             10811 W. Collins Ave
             Lakewood, CO 80215-4440
Trade Name: Spectra Optia Apheresis System
Cleared Date: 25-JUL-2013

BK130065-0  TERUMO BCT
             10811 W. Collins Ave
             Lakewood, CO 80215-4440
Trade Name: Spectra Optia Apheresis System
Cleared Date: 16-JAN-2014

BK130080-0  TERUMO BCT
             10811 W. Collins Ave
             Lakewood, CO 80215-4440
Trade Name: Trima Accel System, Version 6.2
Cleared Date: 19-MAR-2014

BK140151-0  TERUMO BCT
             10811 W. Collins Ave
             Lakewood, CO 80215-4440
Trade Name: Spectra Optia Apheresis System
Cleared Date: 13-AUG-2014

BK150251-0  TERUMO BCT
             10811 W. Collins Ave
             Lakewood, CO 80215-4440
Trade Name: Spectra Optia Apheresis System
Cleared Date: 16-JUL-2015

BK160116-0  TERUMO BCT
             10811 W. Collins Ave
             Lakewood, CO 80215-4440
Trade Name: Trima Accel Automated Blood
            Collection System
Cleared Date: 23-DEC-2016
BK120012-0  TERUMO Corporation
10811 W. Collins Avenue
Lakewood, CO 80215
Trade Name: Spectra Optia Apheresis System
Cleared Date: 09-JUL-2012

BK120017-0  TERUMO Corporation
10811 W. Collins Avenue
Lakewood, CO 80215
Trade Name: Trima Accel Automated Blood Component Collection System
Cleared Date: 31-MAY-2012

BK120040-0  TERUMO Corporation
10811 W. Collins Avenue
Lakewood, CO 80215
Trade Name: Trima Accel System
Cleared Date: 03-OCT-2012

BK120049-0  TERUMO Corporation
10811 W. Collins Avenue
Lakewood, CO 80215
Trade Name: Trima Accel System
Cleared Date: 17-DEC-2012

BK220695-0  THE GID GROUP INC.
901 Front Street
Louisville, CO 80027
Trade Name: GID 700 (K120902)
Cleared Date: 29-MAR-2022

BK220702-0  THIEBAUD SAS
2 impasse des primbois
Margencel, Haute-Savoie FRANCE 74200
Trade Name: ST’RIM (K142073)
Cleared Date: 31-MAR-2022

BK220750-0  THIEBAUD SAS
2 impasse des primbois
Margencel, Haute-Savoie FRANCE 74200
Trade Name: macro st’rim
macro st’rim™
mini st’rim
mini st’rim™
nano st’rim
nano st’rim™
st’rim™
Cleared Date: 26-AUG-2022
Tahoe Chemical R & D
2230 Damon Road
Carson City, NV 89701
Trade Name: Nover Trip Scale Alarm
Cleared Date: 14-JUL-1997

Talisman Ltd.
421 Church Street NE. Suite F
Vienna, VA 22180
Trade Name: Quality Donor System 2004 - 2.0
Cleared Date: 18-OCT-2004

Talisman Ltd.
421 Church Street NE. Suite F
Vienna, VA 22180
Trade Name: Talisman Phlebotomy System Release 1.0
Cleared Date: 27-JUL-2006

Talisman Ltd.
421 Church Street NE. Suite F
Vienna, VA 22180
Trade Name: Quality Donor System - v2.1
Cleared Date: 16-JUL-2007

Talon Medical, Ltd.
18160 Highway 281 N
Suite 108
San Antonio, TX 78232
Trade Name: Cord-X System
Cleared Date: 20-JAN-1999

Tepnel Lifecodes Corporation
550 West Avenue
Stamford, CT 06902
Trade Name: LIFECODES HLA 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

Tepnel Lifecodes Corporation
550 West Avenue
Stamford, CT 06902
Trade Name: LIFECODES HLA Typing Kits (HLA-A,
B, C, DQB, DRB, DRB1) for use with Luminex

Cleared Date: 13-NOV-2008

BK090018-0  Tepnel Lifecodes Corporation
550 West Avenue
Stamford, CT 06902
Trade Name: LIFECODES Evolution Software, version 1.0
Cleared Date: 04-JUN-2009

BK010006-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Automated Blood Component Collection System
Cleared Date: 27-FEB-2002
Cleared Under Gambro BCT, Inc

BK010037-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Platelet collection sets for the COBE Spectra Apheresis System and the Trima Automated Blood Component Collection System.
Cleared Date: 24-SEP-2003
Cleared Under Gambro BCT, Inc

BK010046-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Automated Blood Collection System (Single Stage)
Cleared Date: 18-SEP-2002
Cleared Under Gambro BCT, Inc

BK010050-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Automated Blood Collection System
Cleared Date: 18-SEP-2002
Cleared Under Gambro BCT, Inc

BK020015-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System, Independent Solution
Cleared Date: 15-JUL-2002
Cleared Under Gambro BCT, Inc

BK020041-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: COBE Spectra Apheresis
System/Blood component disposable
collection sets for apheresis
Cleared Date: 23-APR-2003
Cleared Under Gambro BCT, Inc

BK030021-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System - 2.1
Cleared Date: 01-MAY-2003
Cleared Under Gambro BCT, Inc

BK030083-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel
Cleared Date: 14-JAN-2004
Cleared Under Gambro BCT, Inc

BK040069-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Automated Blood Component
Collection System - Blood
Component Sampling Accessory
Cleared Date: 28-OCT-2004
Cleared Under Gambro BCT, Inc

BK040086-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: COBE Spectra Apheresis System &
Trima Automated Blood Component
Collection System
Cleared Date: 15-MAR-2005
Cleared Under Gambro BCT, Inc

BK070001-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System - 3.0
Cleared Date: 27-JUN-2007
Cleared Under Gambro BCT, Inc
BK070066-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System, Version 3.0 with Medical Review Module
Cleared Date: 13-DEC-2007
Cleared Under Gambro BCT, Inc

BK080010-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: The Atreus Whole Blood Processing System
Cleared Date: 27-JUN-2008
Cleared Under Gambro BCT, Inc

BK080029-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel Automated Blood Component Collection System
Cleared Date: 18-MAY-2010
Cleared Under Gambro BCT, Inc

BK140104-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System Version 3.2
Cleared Date: 01-APR-2014

BK140158-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel System Version 6.4
Cleared Date: 29-AUG-2014

BK140180-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Model 81000 Trima Accel System Mobile Pro Package
Cleared Date: 05-NOV-2014

BK140191-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Spectra Optia Apheresis System
Cleared Date: 09-MAR-2015

BK150228-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Vista Information System - 4.0
Cleared Date: 22-SEP-2015

BK150269-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel system
Cleared Date: 06-AUG-2015

BK150321-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel System
Cleared Date: 16-OCT-2015

BK160082-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: T-Cuff
Cleared Date: 19-AUG-2016

BK160108-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: TSCD-II Sterile Tubing Welder with or without Trucise Total System (TM), Model ME-SC203A
Cleared Date: 23-NOV-2016

BK170059-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: Trima Accel (R) Blood Collection System
Cleared Date: 07-JUL-2017

BK170098-0  Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215-4498
Trade Name: TSCD-II Sterile Tubing Welder with or without Trucise Total System (TM)
Cleared Date: 29-SEP-2017
BK170157-0  Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215  
Trade Name: Trima Accel(R) Blood Collection System  
Cleared Date: 06-APR-2018  

BK180231-0  Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215  
Trade Name: Trima Accel(R) Blood Collection System  
Trima Accel® Automated Blood Collection System  
Cleared Date: 17-AUG-2018  

BK180258-0  Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215  
Trade Name: Vista Information System  
Cleared Date: 18-JAN-2019  

BK190332-0  Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215  
Trade Name: Trima Accel Blood Collection System  
Cleared Date: 22-MAY-2019  

BK190333-0  Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215  
Trade Name: TOMEs - 7  
Cleared Date: 03-DEC-2019  

BK210591-0  Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215  
Trade Name: Harvest PRP Separation System  
Harvest PRP Separation System with ACDA (30 mL)  
Harvest PRP Separation System with LP-10  
SmartPrep2 System  
Cleared Date: 11-FEB-2022  

BK210635-0  Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215  
Trade Name: Rika Plasma Bottle
Rika Plasma Donation System
Rika Plasma Separation Set
Cleared Date: 07-MAR-2022

BK210658-0   Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood, CO 80215
Trade Name: IMUGARD® WB PLT Platelet Pooling Set
Cleared Date: 26-AUG-2022

BK820015-0   Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name: Plasmaflex Pooling Bottle
Cleared Date: 12-NOV-1982

BK850017-0   Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name: Plasmaflex Bottles
Cleared Date: 04-NOV-1985

BK860012-0   Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name: Imugard Leukocyte Filter
Cleared Date: 16-MAY-1990

BK890005-0   Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name: Stericell Cell Processor
Cleared Date: 10-OCT-1989

BK890017-0   Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name: Teruflex Transfer Bag
Cleared Date: 18-JUL-1990

BK890032-0   Terumo Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: Immugard-E- Leukocyte Removal From Red Blood Cells
Cleared Date: 18-JUL-1990

BK900028-0   Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name: Terufusion Plasma Transfer Set
Cleared Date: 22-OCT-1990

BK920040-0  Terumo Corporation
2805 East Ana Street
Compton, CA 90221
Trade Name: Venoject II Holder
Cleared Date: 20-MAY-1993

BK950039-0  Terumo Corporation
2100 Cottontail Lane
Somerset, NJ 08873
Trade Name: Teruflex B-600 Terumo Blood Bag without anticoagulant
Cleared Date: 25-AUG-1995

BK950058-0  Terumo Corporation
2100 Cottontail Lane
Somerset, NJ 08873
Trade Name: Terumo Sampling Site Coupler
Cleared Date: 13-NOV-1995

BK860041-0  Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: SCD 312
Cleared Date: 01-JUN-1987

BK970008-0  Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: Terumo Sterile Tubing Welder SC-201A (TSCD)
Cleared Date: 28-MAY-1998

BK970011-0  Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: Terumo Phlebotomy Needle Cap Holder
Cleared Date: 19-JUN-1997

BK000045-0  Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921
Trade Name: Imugard III-PL
Cleared Date: 28-SEP-2001

BK020033-0  Terumo Medical Corporation
BK040082-0  Terumo Medical Corporation  
125 Blue Ball Road  
Elkton, MD 21921  
Trade Name: Imugard III-PL Leukocyte reduction filter  
Cleared Date: 22-MAY-2003

BK070018-0  Terumo Medical Corporation  
125 Blue Ball Road  
Elkton, MD 21921  
Trade Name: TSCD-II Terumo Sterile Tubing Welder  
Cleared Date: 05-APR-2005

BK110071-0  Terumo Medical Corporation  
950 Elkton Blvd  
Elkton, MD 21921  
Trade Name: TRUCISE Total System  
Cleared Date: 22-JAN-2008

BK980002-0  Teva Medical LTD  
482 Hudson Terrace  
Englewood Cliffs, NJ 07632  
Trade Name: SegMed  
Cleared Date: 02-MAR-1998

BK050060-0  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 ABCRDQ Typing Kit  
Cleared Date: 22-APR-2009

BK050058-0  The Surgical Company International  
Terminalweg 19a  
Amersfoort, NETHERLANDS 3821 AJ  
Trade Name: Fluido Blood and Fluid Warmer System  
Cleared Date: 05-MAY-2006
BK070055-0  The Surgical Company International  
Terminalweg 19a  
Amersfoort, NETHERLANDS 3821 AJ  
Trade Name: Fluido Air Guard  
Fluido Compressor  
Fluido IV-Pole  
Fluido Pressure Chamber  
Cleared Date: 15-JAN-2008

BK950067-0  Thermal Transfer Technology  
681 Main Street  
Placerville, CA 95667  
Trade Name: Thermal Ware  
Cleared Date: 14-FEB-1996

BK160044-0  Thermo Electron LED GmbH (a subsidiary of Thermo Fisher Scientific Inc.)  
Am Kalkberg  
Osterode am Harz,  
Trade Name: Thermo Scientific CW3 Cell Washer  
Cleared Date: 07-OCT-2016

BK180198-0  ThermoGenesis Corp  
2700 Citrus Rd  
Rancho Cordova, CA 75741  
Trade Name: AXP II AutoXpress Platform  
Cleared Date: 14-NOV-2018

BK960072-0  Thermogenesis  
3146 Gold Camp Drive  
Suite 206  
Rancho Cordova, CA 95670-6022  
Trade Name: CryoSeal System  
Cleared Date: 12-FEB-1999

BK960074-0  Thermogenesis  
3146 Gold Camp Drive  
Suite 206  
Rancho Cordova, CA 95670-6022  
Trade Name: HemoMatic Blood Collection Monitor  
Cleared Date: 03-APR-1997

BK030011-0  Thermogenesis  
3146 Gold Camp Drive  
Suite 206  
Rancho Cordova, CA 95670-6022  
Trade Name: ThermoGenesis Thawer  
Cleared Date: 10-JUN-2003
BK070006-0  Thermogenesis
2711 Citrus Road
Rancho Cordova, CA 95742
Trade Name: AXP AutoXpress Platform
Cleared Date: 05-OCT-2007

BK100066-0  Thermogenesis
2711 Citrus Road
Rancho Cordova, CA 95742
Trade Name: ThermoGenesis Res-Q60 PRP Device
Cleared Date: 27-MAY-2011

BK900017-0  Thermopol Inc.
2481 B Delta Ln,
Elk Grove Village, IL 60007
Trade Name: Solid State Portable Refrigerator
Cleared Date: 30-AUG-1990

BK940038-0  Thomson & Neilsen, Ltd.
1050 Baxter Road
Ottawa, Ontario, Canada, CANADA
Trade Name: Blood Irradiator Dosimetry System
TN-ID-50
Cleared Date: 18-OCT-1994

BK150289-0  Timestrip UK Ltd.
22 Friars Street
Sudbury
, Suffolk UNITED KINGDOM CO102AA
Trade Name: Timestrip(R) Blood Temp 10 (BT10)
Cleared Date: 14-DEC-2015

BK190363-0  Timestrip UK Ltd.
22 Friars Street
Sudbury
, Suffolk UNITED KINGDOM CO102AA
Trade Name: Timestrip Blood Temp 10
Cleared Date: 22-JUL-2019

BK850007-0  Trayser, Inc.
P.O. Box 83
Cabin John, MD 20818
Trade Name: Trayser DR/DQ Typing Tray Kit
Cleared Date: 25-APR-1985

BK030066-0  Tyco Healthcare
15 Hampshire Street
Mansfield, MA 02048
Trade Name: Kendall LIFETRACE Umbilical Blood Collection Kit
Cleared Date: 03-NOV-2003

BK070037-0  Typenex Medical LLC
303 East Wacker Drive
Suite 311
Chicago, IL 60601
Trade Name: TypeSafe Segment Dispenser
Cleared Date: 05-OCT-2007

BK150351-0  Typenex Medical LLC
303 East Wacker Drive
Suite 311
Chicago, IL 60601
Trade Name: Typesafe 2.0 Segment Piercing Device (Model Number SP0201QD & SP0201QM)
Cleared Date: 28-DEC-2015

BK820012-0  UCLA Tissue Typing Laboratory
1000 Veteran Avenue
Los Angeles, CA 90024
Trade Name: HLA Typing Tray
Cleared Date: 04-MAR-1983

BK970026-0  Utah Medical Products, Inc.
7043 South 300 West
Midvale, UT 84047
Trade Name: Umbilicup
Cleared Date: 28-JAN-1998

BK970027-0  Utah Medical Products, Inc.
7043 South 300 West
Midvale, UT 84047
Trade Name: Umbilicup II Cord Blood System
Cleared Date: 06-JAN-1998

BK010043-0  VEEGEE Scientific
13600 NE 126th Place
Suite A
Kirkland, WA 98034
Trade Name: Atago SP-D2 Refractometer
Cleared Date: 02-JAN-2002

BK870008-0  Val Tech Diagnostics
14 Werner Camp Road
Pittsburgh, PA 15238
Trade Name: Normal Saline-Buffered
Cleared Date: 31-JUL-1987

BK880004-0  Val Tech Diagnostics
14 Werner Camp Road  
Pittsburgh, PA 15238  
Trade Name: Buffered Normal Saline Concentrate  
Cleared Date: 11-APR-1988

BK070044-0  
Verax Biomedical Incorporated  
148 Bartlett Street  
Marlborough, MA 01752  
Trade Name: Platelet PGD Controls  
Platelet PGD Test  
Cleared Date: 17-SEP-2007

BK090028-0  
Verax Biomedical Incorporated  
148 Bartlett Street  
Marlborough, MA 01752  
Trade Name: Platelet PGD Test System  
Cleared Date: 10-NOV-2009

BK110014-0  
Verax Biomedical Incorporated  
148 Bartlett Street  
Marlborough, MA 01752  
Trade Name: Platelet PGD Test System  
Cleared Date: 08-SEP-2011

BK140201-0  
Verax Biomedical Incorporated  
148 Bartlett Street  
Marlborough, MA 01752  
Trade Name: Platelet PGD(R) Test System  
Cleared Date: 13-MAY-2015

BK160087-0  
Verax Biomedical Incorporated  
148 Bartlett Street  
Marlborough, MA 01752  
Trade Name: Platelet PGD Test System  
Cleared Date: 06-APR-2017

BK120008-0  
Vertical Spine, LLC  
2201 Marconi Road  
Wall, NJ 07719  
Trade Name: FIBRINET (R) Autologous PRP System  
Cleared Date: 01-AUG-2012  
Cleared Under Cascade Medical Enterprises, LLC

BK020005-0  
Visible Genetics, Inc.  
700 BAY Street, Suite 1000  
Toronto, Ontario M5G 1Z6 CANADA  
Trade Name: Trugene HIV-1 Genotyping Kit and Open Gene DNA Sequencing System  
Cleared Date: 24-APR-2002
Visible Genetics, Inc.
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 CANADA
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 07-NOV-2002

Visible Genetics, Inc.
700 BAY Street, Suite 1000
Toronto, Ontario M5G 1Z6 CANADA
Trade Name: TRUGENE HIV-1 Genotyping Kit and OpenGene DNA Sequencing System
Cleared Date: 14-MAR-2003

WHITTAKER BIOPRODUCTS, INC.
8830 Biggs Ford Road
Walkersville, MO 21793
Trade Name: ENDOTOXIN CHALLENGE VIALS
Cleared Date: 09-AUG-1991

Wako Chemicals, USA, Inc.
12300 Ford Road, Suite 130
Dallas, TX 75234
Trade Name: Toxinometer ET-201
Cleared Date: 10-FEB-1987

WellSky Corporation
1300 Switzer Rd
Overland Parl, KS 66210
Trade Name: WellSky™ Blood – Emergency Issue 2020 R1
Cleared Date: 12-JUN-2020

Whitman Medical Corporation
990 Raritan Road
Clark, NJ 07066
Trade Name: Safe-T-Vue Irreversible Temperature Indicator
Cleared Date: 12-MAY-1992

Wyndgate Technologies
11121 Sun Center Drive
Suite C
Rancho Cordova, CA 95670
Trade Name: Safe Trace
Cleared Date: 14-APR-1997

Wyndgate Technologies
11060 White Rock Road
Suite 200
Rancho Cordova, CA 95670
Trade Name: SafeTrace TX, version 1.0
Cleared Date: 29-JAN-1999

BK070010-0  Wyndgate Technologies
            4925 Robert J. Matthews Parkway
            Suite 100
            El Dorado Hills, CA 95762
Trade Name: ElDorado Donor Doc - 1.0.0
Cleared Date: 23-MAY-2007

BK070064-0  Wyndgate Technologies
            4925 Robert J. Matthews Parkway
            Suite 100
            El Dorado Hills, CA 95762
Trade Name: ElDorado Donor - 1.0.0
Cleared Date: 13-FEB-2008

BK090026-0  Wyndgate Technologies
            4925 Robert J. Matthews Parkway
            Suite 100
            El Dorado Hills, CA 95762
Trade Name: Safe Trace Tx
Cleared Date: 03-SEP-2009

BK090033-0  Wyndgate Technologies
            4925 Robert J. Matthews Parkway
            Suite 100
            El Dorado Hills, CA 95762
Trade Name: ElDorodo Donor Doc
Cleared Date: 28-OCT-2009

BK090063-0  Wyndgate Technologies
            4925 Robert J. Matthews Parkway
            Suite 100
            El Dorado Hills, CA 95762
Trade Name: Test Result Interface for ElDorado Donor
Cleared Date: 20-NOV-2009

BK100002-0  Wyndgate Technologies
            4925 Robert J. Matthews Parkway
            Suite 100
            El Dorado Hills, CA 95762
Trade Name: Component Manufacturing Interface for ElDorado Donor
Cleared Date: 24-FEB-2010

BK860005-0  bioMerieux, Inc.
            5300 S. Portland Avenue
Oklahoma City, OK 73119
Trade Name: Plasma Collection Bag
Cleared Date: 19-DEC-1986
Cleared Under BioMerieux, Inc.

BK870019-0 bioMerieux, Inc.
5300 S. Portland Avenue
Oklahoma City, OK 73119
Trade Name: Quik-Chek
Cleared Date: 19-MAY-1988
Cleared Under BioMerieux, Inc.

BK880003-0 bioMerieux, Inc.
5300 S. Portland Avenue
Oklahoma City, OK 73119
Trade Name: Therapeutic Plasmapheresis Collection Bag
Cleared Date: 11-MAR-1988
Cleared Under BioMerieux, Inc.

BK920037-0 bioMerieux, Inc.
5300 S. Portland Avenue
Oklahoma City, OK 73119
Trade Name: PEG+
Cleared Date: 21-OCT-1993
Cleared Under BioMerieux, Inc.

BK960026-0 bioMerieux, Inc.
100 Akzo Avenue
Durham, NC 27712
Trade Name: Status Symbol TM II System Software
Cleared Date: 16-MAR-1999
Cleared Under Organon Teknika Corporation

BK000042-0 bioMerieux, Inc.
100 Akzo Avenue
Durham, NC 27712
Trade Name: BacT/ALERT Culture Bottles
Cleared Date: 15-FEB-2002
Cleared Under BioMerieux, Inc.

BK020022-0 bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT SN Culture Bottle
Cleared Date: 10-OCT-2002
Cleared Under BioMerieux, Inc.

BK020023-0 bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT SA Culture Bottle
Cleared Date: 10-OCT-2002
Cleared Under BioMerieux, Inc.

BK020060-0  bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: NuclieSens HIV-1 QT RNA External Controls
Cleared Date: 18-DEC-2002
Cleared Under BioMerieux, Inc.

BK030034-0  bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPN Culture Bottle
Cleared Date: 18-JUL-2003
Cleared Under BioMerieux, Inc.

BK030035-0  bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPA Culture Bottle
Cleared Date: 06-AUG-2003
Cleared Under BioMerieux, Inc.

BK030075-0  bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPN Culture Bottles
Cleared Date: 08-MAR-2004
Cleared Under BioMerieux, Inc.

BK030076-0  bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPA Culture Bottles
Cleared Date: 08-MAR-2004
Cleared Under BioMerieux, Inc.

BK050037-0  bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPA Culture Bottle
Cleared Date: 27-DEC-2005
Cleared Under BioMerieux, Inc.

BK050043-0  bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Trade Name: BacT/ALERT BPN Culture Bottle
Cleared Date: 27-DEC-2005
Cleared Under BioMerieux, Inc.

BK170142-0  bioMerieux, Inc.
595 Anglum Road
Hazelwood, MO 63042
Trade Name: BacT/ALERT® BPA Culture Bottle
BacT/ALERT® BPN Culture Bottle
Cleared Date: 01-FEB-2018

BK180266-0  bioMerieux, Inc.
595 Anglum Road
Hazelwood, MO 63042
Trade Name: BACT/ALERT® BPA Culture Bottle
BACT/ALERT® BPN Culture Bottle
Cleared Date: 29-NOV-2018

BK200472-0  bioMerieux, Inc.
595 Anglum Road
Hazelwood, MO 63042
Trade Name: BACT/ALERT BPA Culture Bottle
BACT/ALERT BPN Culture Bottle
Cleared Date: 20-MAY-2020

BK040018-0  sienna partners
P.O. Box 103
Baldwin, MD 21013
Trade Name: Vacuette EDTA K2 tube; Vacuette EDTA K3 tube
Cleared Date: 28-JUL-2004