Currently Approved CBER Device Premarket Applications (PMAs) As of 31-MAY-2021

BP090080-0  Abbott Laboratories  
            100 Abbott Park Road  
            Abbott Park, IL 60064-3500  
            Trade Name: ARCHITECT HIV Ag/Ab Combo Assay  
            Approved Date: 18-JUN-2010

BP060002-0  Abbott Molecular  
            1300 E. Touhy Avenue  
            Des Plaines, IL 60018  
            Trade Name: Abbott RealTime HIV-1 Amplification Reagent Kit  
                    Abbott RealTime HIV-1 Calibrator Kit  
                    Abbott RealTime HIV-1 Control Kit  
            Approved Date: 11-MAY-2007  
            Approved Under ABBOTT Molecular, Inc.

BP200455-0  Abbott Molecular, Inc.  
            1300 East Touhy Ave  
            Des Plaines, IL 60018  
            Trade Name: Alinity m HIV-1  
            Approved Date: 02-JUL-2020

BP120037-0  Alere Scarborough Inc  
            10 Southgate Road  
            Scarborough, ME 04074  
            Trade Name: Alere DetermineTM HIV-1/2 Ag/Ab Combo  
            Approved Date: 08-AUG-2013  
            Approved Under Alere Scarborough

BP090022-0  Avioq, Inc.  
            9700 Great Seneca Hwy.  
            Rockville, MD 20850  
            Trade Name: Avioq HIV-1 Microelisa System  
            Approved Date: 21-SEP-2009

BP180279-0  Avioq, Inc.  
            104 TW Alexander Dr  
            Building 6  
            PO Box 12808  
            Research Triangle Park, NC 27709  
            Trade Name: VioOne HIV Profile Supplemental Assay  
            Approved Date: 19-OCT-2020

BP170122-0  Avita Medical  
            28159 Avenue Stanford  
            Suite 220  
            Valencia, CA 91355-2271  
            Trade Name: ReCell Autologous Cell Harvesting Device  
            Approved Date: 20-SEP-2018
BP140111-0  Bio-Rad Laboratories
6565 185th Ave NE
Clinical Diagnostics Group
Redmond, WA 98052-5039
Trade Name: BioPlex? 2200 HIV Ag-Ab
Approved Date: 23-JUL-2015

BP040046-0  Bio-Rad Laboratories, Inc.
6565 185th Avenue NE
Redmond, WA 98052
Trade Name: Multispot HIV-1/HIV-2 Rapid Test
Approved Date: 12-NOV-2004
Approved Under Bio-Rad Laboratories

BP100064-0  Bio-Rad Laboratories, Inc.
6565 185th Avenue NE
Redmond, WA 98052
Trade Name: GS HIV Combo Ag/Ab EIA
Approved Date: 22-JUL-2011
Approved Under Bio-Rad Laboratories

BP140120-0  Bio-Rad Laboratories, Inc.
6565 185th Avenue NE
Redmond, WA 98052
Trade Name: Bio-Rad Geenius HIV 1/2 Supplemental Assay
Approved Date: 24-OCT-2014

BP130026-0  BioArray Solutions, Ltd.
35 Technology Drive
Suite 100
Warren, NJ 07059
Trade Name: Immucor PreciseType™ Human Erythrocyte Antigen Molecular BeadChip Test
Approved Date: 21-MAY-2014

BP130076-0  Cerus Corporation
2550 Stanwell Drive
Concord, CA 94520
Trade Name: INTERCEPT(R) Blood System for Plasma
Approved Date: 16-DEC-2014

BP140143-0  Cerus Corporation
2550 Stanwell Drive
Concord, CA 94520
Trade Name: INTERCEPT(R) Blood System for Platelets
Approved Date: 18-DEC-2014

BP050009-0  Chembio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, NY 11763
Trade Name: Chembio HIV Reactive/Nonreactive Controls
SURE CHECK HIV 1/2 ASSAY
Approved Date: 25-MAY-2006

BP050010-0  Chembio Diagnostic Systems, Inc.
            3661 Horseblock Road
            Medford, NY 11763
Trade Name: Chembio HIV Reactive/Nonreactive Controls
            HIV 1/2 STAT-PAK ASSAY
Approved Date: 25-MAY-2006

BP120032-0  Chembio Diagnostic Systems, Inc.
            3661 Horseblock Road
            Medford, NY 11763
Trade Name: DPP HIV 1/2 Assay
Approved Date: 19-DEC-2012

BP180191-0  Chembio Diagnostic Systems, Inc.
            3661 Horseblock Road
            Medford, NY 11763
Trade Name: DPP? HIV-Syphilis System
Approved Date: 01-OCT-2020

BP190437-0  DiaSorin, Inc.
            1951 Northwestern Ave
            Stillwater, MN 55082-0285
Trade Name: LIAISON? XL MUREX Control HIV Ab/Ag HT
            LIAISON? XL MUREX HIV Ab/Ag HT
Approved Date: 25-NOV-2020

BP850001-0  Fenwal Inc
            Three Corporate Drive
            2nd Floor
            Lake Zurich, IL 60047
Trade Name: Autopheresis-C Plasmapheresis System
Approved Date: 24-MAR-1986
Approved Under Baxter Healthcare Corporation

BP150318-0  Hologic, Inc.
            10210 Genetic Center Drive
            San Diego, CA 92121
Trade Name: Aptima HIV-1 Quant Dx assay
Approved Date: 22-DEC-2016

BP950002-0  Home Access Health Corporation
            2401 West Hassell Road
            Suite 1510
            Hoffman Estates, IL 60169-5200
Trade Name: Home Access HIV-1 Test System
Approved Date: 22-JUL-1996

BP000009-0  Maxim Biomedical Inc  
1440 Fourth Street  
Berkeley, CA 94710  
Trade Name: Calypte HIV-1 Urine EIA  
Approved Date: 12-JAN-2001  
Approved Under Calypte Biomedical Corporation

BP010009-0  Maxim Biomedical Inc  
1265 Harbor Bay Parkway  
Alameda, CA 94502  
Trade Name: Cambridge Biotech HIV-1 Urine Western Blot  
Approved Date: 21-JUN-2001  
Approved Under Calypte Biomedical Corporation

BP000023-0  MedMira Labs  
155 Chain Lake Drive, Bayers Lake  
Halifax, Nova Scotia CANADA B3S 1B3  
Trade Name: MedMira Rapid HIV Test  
Approved Date: 16-APR-2003

BP910001-0  OraSure Technologies, Inc  
8505 SW Creekside Place  
Beaverton, OR 97005  
Trade Name: Orasure HIV-1 Oral Specimen Collection Device  
Approved Date: 23-DEC-1994  
Approved Under OraSure Technologies

BP950004-0  OraSure Technologies, Inc  
220 East First Street  
Bethlehem, PA 18015-1360  
Trade Name: OraSure HIV-1 Western Blot Kit  
Approved Date: 03-JUN-1996  
Approved Under Epitope, Inc.

BP010047-0  OraSure Technologies, Inc  
150 Webster Street  
Bethlehem, PA 18015-1389  
Trade Name: OraQuick ADVANCE Rapid HIV-1/2 Antibody Test  
Approved Date: 07-NOV-2002  
Approved Under OraSure Technologies

BP120001-0  OraSure Technologies, Inc  
220 East First Street  
Bethlehem, PA 18015-1360  
Trade Name: OraQuick® In-Home HIV Test  
Approved Date: 03-JUL-2012

BP953200-0  Organogenesis, Inc.
150 Dan Road
Canton, MA 02021
Trade Name: Apligraf

Approved Date: 22-MAY-1998

BP960700-0 Organogenesis, Inc.
150 Dan Road
Canton, MA 02021
Trade Name: Dermagraft-TC (temporary covering)

Approved Date: 18-MAR-1997

BP003600-0 Organogenesis, Inc.
150 Dan Road
Canton, MA 02021
Trade Name: Dermagraft

Approved Date: 28-SEP-2001

BP011600-0 Ortec International, Inc.
3960 Broadway, 2nd Floor
New Yoir, NY 10032
Trade Name: Orce

Approved Date: 31-AUG-2001

BP050051-0 Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101
Trade Name: VITROS Immunodiagnostic Products Anti-HIV 1+2 Calibrator
VITROS Immunodiagnostic Products Anti-HIV 1+2 Reagent Pack

Approved Date: 27-MAR-2008

BP160122-0 Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626-5101
Trade Name: VITROS Immunodiagnostic Products HIV Combo Calibrator
VITROS Immunodiagnostic Products HIV Combo Reagent Pack

Approved Date: 13-DEC-2017

BP170154-0 Progenika Biopharma, S.A.
Ibaizabal bidea, Edificio 504
Parque Tecnologic de Bizkaia
Derio, Bizkaia,
Trade Name: ID CORE XT
Approved Date: 11-OCT-2018

BP160050-0  Roche Diagnostics operations, Inc.
9115 Hague Road
Indianapolis, IN 46250
Trade Name: Elecsys HIV combi PT
Approved Date: 21-JUN-2017
Approved Under Roche Diagnostics

BP190403-0  Roche Diagnostics operations, Inc.
9115 Hague Road
Indianapolis, IN 46250
Trade Name: Elecsys HIV Duo
Approved Date: 10-APR-2020
Approved Under Roche Diagnostics

BP050069-0  Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton,, CA 94588-2722
Trade Name: COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, 48 Tests
COBAS AmpliPrep/COBAS TaqMan Wash Reagent, 5.1 L
Approved Date: 11-MAY-2007

BP150262-0  Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton,, CA 94588-2722
Trade Name: cobas HIV-1
Approved Date: 18-DEC-2015

BP190360-0  Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton,, CA 94588-2722
Trade Name: cobas? HIV-1/HIV-2 Qualitative
Approved Date: 12-AUG-2020

BP050030-0  Siemens Healthcare Diagnostics
511 Benedict Ave
Tarrytown, NY 10591
Trade Name: ADVIA Centaur HIV 1/0/2 Enhanced ReadyPack Reagents
Approved Date: 18-MAY-2006
Approved Under Bayer HealthCare

BP140103-0  Siemens Healthcare Diagnostics, Inc.
511 Benedict Ave
Tarrytown, NY 10591
Trade Name: ADVIA Centaur HIV Ag/Ab Combo (CHIV) Assay
Approved Date: 08-JUN-2015

BP060001-0  ThermoGenesis Corp
2711 Citrus Road
Rancho Cordova, CA 95742
Trade Name: CryoSeal FS System
Approved Date: 26-JUL-2007
Approved Under Thermogenesis

BP030025-0  Trinity Biotech
IDA Business Park
Southern Cross Road,
, Bray, Co. Wicklow IRELAND
Trade Name: Uni-Gold Recombigen HIV-1
Approved Date: 23-DEC-2003
Approved Under Trinity Biotech plc

BP090032-0  biolytical Laboratories, Inc
1108-13351 Commerce Parkway
Richmond, BC, British Columbia CANADA V6V 2X7
Trade Name: INSTI¿ HIV-1 Antibody Test Kit
Approved Date: 29-NOV-2010