Currently Approved CBER Device Premarket Applications (PMAs) As of 31-DEC-2019

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.

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

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: Multi-spot 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.
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

BP850001-0 Fenwal Inc
Three Corporate Drive
2nd Floor
Lake Zurich, IL 60047
Trade Name: Autoopheresis-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 York, NY 10032
Trade Name: Orcel
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 Tecnológico de Bizkaia
Derio, Bizkaia,
Trade Name: ID CORE XT
Approved Date: 11-OCT-2018

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

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

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
2711 Citrus Road
Rancho Cordova, CA 95742
Trade Name: CryoSeal FS System  
Approved Date: 26-JUL-2007

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