Currently Approved CBER Device Premarket Applications (PMAs) As of 30-SEP-2022

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
<table>
<thead>
<tr>
<th>Code</th>
<th>Company</th>
<th>Address</th>
<th>Trade Name</th>
<th>Approved Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP040046-0</td>
<td>Bio-Rad Laboratories, Inc.</td>
<td>6565 185th Avenue NE</td>
<td>Multispot HIV-1/HIV-2 Rapid Test</td>
<td>12-NOV-2004</td>
<td></td>
</tr>
<tr>
<td>BP100064-0</td>
<td>Bio-Rad Laboratories, Inc.</td>
<td>6565 185th Avenue NE</td>
<td>GS HIV Combo Ag/Ab EIA</td>
<td>22-JUL-2011</td>
<td></td>
</tr>
<tr>
<td>BP140120-0</td>
<td>Bio-Rad Laboratories, Inc.</td>
<td>6565 185th Avenue NE</td>
<td>Bio-Rad Geenius HIV 1/2 Supplemental Assay</td>
<td>24-OCT-2014</td>
<td></td>
</tr>
<tr>
<td>BP130026-0</td>
<td>BioArray Solutions, Ltd.</td>
<td>35 Technology Drive</td>
<td>Immucor PreciseType™ Human Erythrocyte Antigen Molecular BeadChip Test</td>
<td>21-MAY-2014</td>
<td></td>
</tr>
<tr>
<td>BP130076-0</td>
<td>Cerus Corporation</td>
<td>2550 Stanwell Drive</td>
<td>INTERCEPT(R) Blood System for Plasma</td>
<td>16-DEC-2014</td>
<td></td>
</tr>
<tr>
<td>BP140143-0</td>
<td>Cerus Corporation</td>
<td>2550 Stanwell Drive</td>
<td>INTERCEPT(R) Blood System for Platelets</td>
<td>18-DEC-2014</td>
<td></td>
</tr>
<tr>
<td>BP050009-0</td>
<td>Chembio Diagnostic Systems, Inc.</td>
<td>3661 Horseblock Road</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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: 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 Tecnologico 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