Currently Approved CBER Device Premarket Applications (PMAs) As of 31-OCT-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 Determine 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: 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

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
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