Currently Approved CBER Device Premarket Applications (PMAs)  
As of June 06, 2017  
Sorted by Applicant Name

| 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, Inc.  
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  
10 Southgate Road  
Scarborough, ME 04074  
Trade Name: Alere Determine™ HIV-1/2 Ag/Ab Combo  
Approved Date: 08-AUG-2013 |
| BP090022-0 | Avioq, Inc.  
9700 Great Seneca Hwy.  
Rockville, MD 20850  
Trade Name: Avioq HIV-1 Microelisa System  
Approved Date: 21-SEP-2009 |
| 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 |
| 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 |
| BP090032-0 | bioLytical Laboratories, Inc |
1108-13351 Commerce Parkway
Richmond, BC, British Columbia Canada V6V 2X7
Trade Name: INSTIA® HIV-1 Antibody Test Kit
Approved Date: 29-NOV-2010

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

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
| BP950005-0 | Roche Molecular Systems, Inc.  
1080 US Highway 202  
Branchburg, Somerville, NJ 08876-3771 |
| Trade Name: Roche Amplicor HIV-1 Monitor (tm) Test  
Approved Date: 03-JUN-1996 |
| BP050069-0 | Roche Molecular Systems, Inc.  
4300 Hacienda Drive  
P.O. Box 9002  
Pleasanton,, CA 94588-0900 |
| 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 |
| BP960700-0 | Shire Regenerative Medicine, Inc.  
11095 Torreyana Road  
San Diego, CA 92121 |
| Trade Name: Dermagraft-TC (temporary covering)  
Approved Date: 18-MAR-1997 |
| BP050030-0 | Siemens Healthcare Diagnostics  
511 Benedict Ave.  
Tarrytown, NY 10591 |
| Trade Name: ADVIA Centaur HIV 1/O/2 Enhanced ReadyPack Reagents  
Approved Date: 18-MAY-2006  
Approved Under Bayer HealthCare |
| 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 |