Currently Approved CBER Device Premarket Applications (PMAs)
As of Mar 06, 2015
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 DetermineTM 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

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

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
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

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

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

BP000028-0 Siemens Medical Solutions Diagnostics
P.O. Box 2466
Berkeley, CA 94702-0466
Trade Name: Quntiplex HIV-1 RNA 3.0 Assay (bDNA)
Approved Date: 11-SEP-2002
Approved Under Bayer Corporation

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