

Currently Approved CBER Device Premarket Applications (PMAs)
As of July 01, 2014
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

BP090032-0 bioLytical Laboratories, Inc
1108-13351 Commerce Parkway
Richmond, BC, British Columbia Canada V6V 2X7
Trade Name: INSTI₂ 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

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

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

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 Epitepe, 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

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 Immunodiagnositics Products Anti-HIV 1+2
Calibrator
VITROS Immunodiagnositics 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

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 1/0/2 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