

Currently Approved CBER Device Premarket Applications (PMAs)  
As of September 04, 2012  
Sorted by Applicant Name

BP060002 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

BP090080 Abbott Laboratories  
100 Abbott Park Road  
Abbott Park, IL 60064-3500  
Trade Name: ARCHITECT HIV Ag/Ab Combo Assay  
Approved Date: 18-JUN-2010

BP090022 Avig, Inc.  
9700 Great Seneca Hwy.  
Rockville, MD 20850  
Trade Name: Avig HIV-1 Microelisa System  
Approved Date: 21-SEP-2009

BP090032 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 Bio-Rad Laboratories  
6565 185th Avenue NE  
Redmond, WA 98052  
Trade Name: Multispot HIV-1/HIV-2 Rapid Test  
Approved Date: 12-NOV-2004

BP100064 Bio-Rad Laboratories  
6565 185th Avenue NE  
Redmond, WA 98052  
Trade Name: GS HIV Combo Ag/Ab EIA  
Approved Date: 22-JUL-2011

BP050009 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 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

BP850001 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 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 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 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 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 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 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 Epi tope, Inc.

BP010047 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 OraSure Technologies, Inc  
220 East First Street  
Bethlehem, PA 18015-1360  
Trade Name: OraQuick® In-Home HIV Test

Approved Date: 03-JUL-2012

BP050051 Ortho-Clinical Diagnostics, Inc.  
100 Indigo Creek Drive  
Rochester, NY 14626-5101  
Trade Name: VITROS Immunodiagnostics Products  
Anti-HIV 1+2 Calibrator  
VITROS Immunodiagnostics Products  
Anti-HIV 1+2 Reagent Pack  
Approved Date: 27-MAR-2008

BP950005 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 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 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 Siemens Medical Solutions Diagnostics  
P. O. Box 2466  
Berkeley, CA 94702-0466  
Trade Name: Quantipl ex HIV-1 RNA 3.0 Assay  
(bDNA)  
Approved Date: 11-SEP-2002  
Approved Under Bayer Corporation

BP060001 Thermogenesis  
2711 Citrus Road  
Rancho Cordova, CA 95742  
Trade Name: CryoSeal FS System  
Approved Date: 26-JUL-2007

BP030025 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