

JUL 22 2002

Abbreviated 510(k) Submission  
for Mission Diagnostic Reagents  
on pH/Blood Gas &/or Electrolyte Analyzers

1. **Submitter's Name & Address**

Mission Diagnostics  
331 Fiske St  
Holliston MA 01746  
FAX: 508-429-0452

**Contact Person:**

Linda M Stundtner  
QA/RA Manager  
508-429-0450

Establishment Registration Number: 300-36-56-721

Date of Preparation: June 19, 2002

2. **Identification of the Device:**

Proprietary/Trade name:	Calibrating Material, Buffers, Standards
Common or usual name	Calibrators for ISE and/or pH/Blood Gas automated systems
Classification name:	Calibrator, secondary
Device Classification	II
Regulation Number:	21 CFR § 862.1150
Panel:	Chemistry (75)
Product Code:	JIT

- Mission manufactures calibrators intended to serve as direct replacements to like named products manufactured by Original Equipment Manufactures (OEM)

**3. Predicate Device:****Substantial Equivalence Table of Product PN's & Trade Names**

Mission Product		OEM Equivalent	
DA-D100D	ISE Standard C	Dade Dimension® ISE Standard C	D100
DA-D102D	ISE Standard A	Dade Dimension® ISE Standard A	D102
DA-D103AD	ISE Standard B	Dade Dimension® ISE Standard B	D103A
DA-D200D	ISE Standard C	Dade Dimension® ISE Standard C	D200
DA-D202D	ISE Standard A	Dade Dimension® ISE Standard A	D202
DA-S540D	IMT Standard A	Dade MultiPLY® IMT Standard A	S540
DA-S550D	IMT Standard B	Dade MultiPLY® IMT Standard B	S550
DA-S560D	IMT Standard C	Dade MultiPLY® IMT Standard C	S560
RO-46997D	ISE Standard 1	Roche Standard 1 for Cobas® ISE Module	46997
RO-46998D	ISE Standard 2	Roche Standard 2 for Cobas® ISE Module	46998
RD-943118D	Red Cal S1556	S1556 Code No. 943-118 Red Calibrating Solution (High pH)	
RD-943117D	Green Cal S1546	S1546 Code No. 943-117 Green Calibrating Solution (Low pH)	
RD-943791D	Cal. Sol. 7.4; 3 S1565	S1565 Code No. 943-791 Calibrating Solution 1, Red 3	
RD-943792D	Cal. Sol. 6.8; 4 S1575	S1575 Code No. 943-792 Calibrating Solution 2, Red 4	
RD-943831D	Cal. Sol. 1; 3 S1585	S1585 Code No. 943-831 Calibrating Solution 1, Blue 3	
RD-943832D	Cal. Sol. 2; 4 S1595	S1595 Code No. 943-832 Calibrating Solution 2, Blue 4	
RD-943837D	Cal 1; S1545	S1545 Code No. 943-837 Calibrating Solution 1, red	
RD-943839D	Cal 2; S1555	S1555 Code No. 943-839 Calibrating Solution 2, green	
RD-943959D	Cal 1; 9 S1580	S1580 Code No. 943-959 Calibrating Solution 1, Red 9	
RD-943960D	Cal 2; 10 S1590	S1590 Code No. 943-960 Calibrating Solution 2, Red 10	
IL-03336004D	7.384 pH Buffer	33360 IL Test™ 7.384 pH Reference Buffer	
IL-03106004D	6.840 pH Buffer	31060 IL Test™ 6.840 pH Reference Buffer	
IL-09831804D	Cal 1	09831800 IL Test™ Cal 1	
IL-09831904D	Cal 2	09831900 IL Test™ Cal 2	

**4. Device Description:**

- The Calibrators for the OEM Instruments are aqueous reagents with salts added to obtain desired analyte levels to provide calibration of the electrodes and rinse the sample path.
- **Intended Use:**
  - The reagents are intended for use on equivalent OEM Instruments.
  - The OEM is the original equipment manufacturer of the instruments and the predicate reagents, which are necessary for the continued operation and use of the instruments.
  - Mission uses a similar composition, description and packaging as that used by the OEM in its products, as shown in the packaging section of this submission.

**5. Performance Characteristics:**

Precision and correlation data are collected per:

- SOP23-01-02 Performance Study Protocol for 510(k) Submission
- Data for each instrument and each run are recorded on SOP23-03F Performance Study Record Sheet. (See Attachment Section for Copy of Procedure and Data Record Sheet)

510(k) Submission for Mission Diagnostics Reagents on pH/BG &/or Electrolyte Analyzers



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUL 22 2002

Ms. Linda Stundtner  
QA/RA Manager  
Diamond Diagnostics Inc.  
Mission Diagnostics  
333 Fiske Street  
Holliston, MA 01746

Re: k022027  
Trade/Device Name: Mission Diagnostic Calibrating Reagents for pH/BG &/or Electrolyte Analyzers  
Regulation Number: 21 CFR 862.1150  
Regulation Name: Calibrator  
Regulatory Class: Class II  
Product Code: JIT  
Dated: June 19, 2002  
Received: June 21, 2002

Dear Ms. Stundtner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

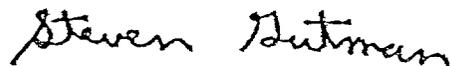
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory-Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number K022027Device Name: Mission Diagnostic Calibrating Reagents for pH/BG &/or Electrolyte Analyzers**Indication For Use:**

The products encompassed by this request are intended for in-vitro diagnostics use and are intended for use in calibrating the electrodes and flushing the sample flow path of the equivalent OEM Analyzers.

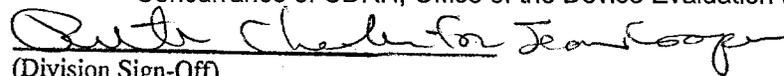
**Substantial Equivalence Table of Product PN's & Trade Names**

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DA-D200D	ISE Standard C	Dade Dimension® ISE Standard C D200
DA-D202D	ISE Standard A	Dade Dimension® ISE Standard A D202
DA-S540D	IMT Standard A	Dade MultiPLY® IMT Standard A S540
DA-S550D	IMT Standard B	Dade MultiPLY® IMT Standard B S550
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IL-09831804D	Cal 1	09831800 IL Test™ Cal 1
IL-09831904D	Cal 2	09831900 IL Test™ Cal 2

- Mission reagents are intended to serve as direct replacements to like named products manufactured by the OEM.
- The products encompassed are to be handled using normal laboratory precautions.
- Sodium Azide is NOT added to any of the formulations

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of the Device Evaluation (ODE)



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K022027

(Optional format 3-10-98)

510(k) Submission for Mission Diagnostics Reagents on pH/BG &amp;/or Electrolyte Analyzers