K033063

DEC 1 2 2003

510(k) Summary
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 Stundtner
QA/RA Manager
508-429-0450

Establishment Registration Number: 3003656721

Date of Preparation: Sept 22, 2003

2. **Identification of the Device:**

Proprietary/Trade name:	Mission Controls™
Common or usual name	Quality Control material (assay and unassayed)
Classification name:	Control s for Blood Gases (assay and unassayed)
Device Classification	I
Regulation Number:	21 CFR § 862.1660
Panel:	Chemistry (75)
Product Code:	JJS

3. **Predicate Device:**

Substantial Equivalence Table of Product PN's & Trade Names

Mission Diagnostics		OEM Equivalent			
		Predicate Device			Cleared Date
DD-92001	Mission Control Level 1	A700-001	ALKOntrol 1	K950902	03-30-1995
DD-92002	Mission Control Level 2	A700-002	ALKtOnrol 2		
DD-92003	Mission Control Level 3	A700-003	ALKOntrol 3		
DD-92123	Mission Control Level 1, 2, 3	A700-123	ALKOntrol TriLevel		
DD-92004	Mission Control Level 4	A500-004	ALKOntrol + ™HIGH O_2		

Mission Controls are used for pH/Blood Gas and Electrolyte Analyzers to estimate test imprecision and to detect systematic deviations that may occur because of instrument or reagent variation.

4. **Device Description:**

- Mission Controls are used for pH/Blood Gas and Electrolyte Analyzers to estimate test imprecision and to detect systematic deviations that may occur because of instrument or reagent variation.
- Mission Controls are aqueous based tonometered controls
- **Intended Use:**

- intended for for pH/Blood Gas and Electrolyte Analyzers to estimate test imprecision and to detect systematic deviations that may occur because of instrument or reagent variation.

- Mission uses a similar composition, description and packaging as that used by the predicate in its products, as shown in the packaging section of this submission.

5. Performance

- Stability studies were done per SOP23-01-03
- Stabilities studies support a 3 year shelf life

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 12 2003

Diamond Diagnostics, Inc.
c/o Ms. Linda M. Stundtner
QA/RA Manager
Mission Diagnostics
331 Fiske Street
Holliston, MA 01746

Re: k033063
Trade/Device Name: Mission Diagnostic ISE pH/Blood Gas Controls for pH/BG &/or Electrolyte Analyzers
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJS
Dated: September 22, 2003
Received: September 29, 2003

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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 Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

5. New Indications of use form:

510(k(Number K033063

Device Name: Mission Diagnostic ISE pH/Blood Gas Controls for pH/BG &/or Electrolyte Analyzers

Indication For Use:

- There are 4 levels of QC encompassed in this request. Levels 1,2,3 cover the Low Mid High of the clinical range for the analytes included in the QC. Level 4 is to check at High O2 level.
- Mission Controls are intended for six systems:

AVL Scientific
945, 947
990, 995
Compact Series
982, 983, 985
986
984, 987
OMNI
9110, 9140
9120, 9130
9180, 9181

Ciba-Corning/Bayer
238
248
348
278
280
288
664
614, 644
634
654
800 Series

IL
1304, 1306, 1312
BG3
BGE
1610, 1620
1630, 1640, 1650

NOVA
Electrolyte Systems
Stat Profile 1-5

Radiometer
ABL 3, 30
ABL 300, 330
ABL 5
ABL, 50, 500, 520
ABL 505
ABL 600, 610, 620
EML-100

Medica, Shapparelli, Medarini
EasyLyte Na/K, Na/K/Cl, Na/K/Li, Na/K/Cl/Li

- The products encompassed by this request are intended for in-vitro diagnostics use and are intended for pH/Blood Gas – (pH, pCO2, pO2), and Electrolyte – (Na, K, Cl, Ca, Li, TOC2) Analyzers to estimate test imprecision and to detect systematic deviations that may occur because of instrument or reagent variation.
- The products encompassed are to be handled using normal laboratory precautions.

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

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

Carol C Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

✓ Prescription use

510(k) K033063