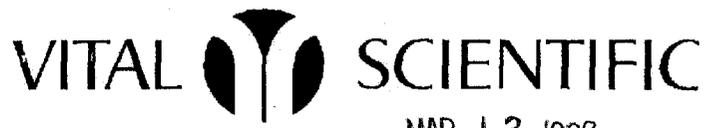


K973628



USA: One Gateway Center, Suite 415 Newton, MA 02158
1-617-527-9933, Ext. 22 Fax: 1-617-527-8230

NL: van Rensselaerweg 4, Spankeren 6956AV, NL
-31-313-43500 Fax:31-313-427807

September 19, 1997

Premarket Notification [510(k)] Summary
for the VITALAB FLEXOR Clinical Laboratory Analysis and Reagent System

Device Name:

Vitalab Flexor (In-vitro diagnostic system). The Vitalab Flexor is also tradenamed the Vitalab Selectra 2 and the Vitalab Viva. References in this document submission may use either of the two names interchangeably.

Common Name:

Automated chemistry analyzer, micro, for clinical use.

Classification Name:

Analyzer, chemistry, micro, for clinical use - has been classified as Class I devices, as per 21 CFR 862.2170. This device is intended for clinical use in conjunction with certain materials to measure a variety of analytes.

Establishment Registration:

Vital Scientific NV, a company established under the laws of the Netherlands, with headquarters at van Rensselaerweg 4, Spankeren, 6956 AV, The Netherlands and with a USA branch office located at One Gateway Center, Suite 415, Newton, MA 02158. Vital Scientific is a registered as a medical device manufacturer under files number 8030478. All instruments are manufactured in the Netherlands. Contact person: Israel M. Stein MD.

Performance Standards:

There are no performance standards for these devices.

Labeling:

This device is labeled in accordance with 21 CFR 809.10.

Summary description of device:

A random access, automated Clinical Micro-Chemistry Analyzer with a throughput of up to 180 test per hour which is intended for clinical use in conjunction with certain materials to measure a variety of analytes, including applications in clinical chemistry, monitoring drugs of abuse and in therapeutic drug monitoring.

Substantial Equivalence:

The Vitalab Flexor System is substantially equivalent to the Roche Cobas Mira presently in distribution in the United States. The Vitalab Flexor System has the same technological characteristics and intended use as these systems. These systems are automated micro-chemistry analyzers intended for clinical use in conjunction with certain materials to measure a variety of analytes (21 CFR 862.2170).

We are including data on twenty-nine (29) representative Clinical Chemistry analytes manufactured by Trace Scientific Pty. Ltd., seven (7) representative analytes for Drugs of Abuse manufactured by Behring Diagnostics and two (2) representative analytes for therapeutic drug monitoring, manufactured by Behring Diagnostics. All of these analytes are presently 510(k) approved under separate submissions by their respective companies. These analytes were chosen because they are representative of the reaction types to be processed on the analyzer.

Thirty-eight (38) representative methods were selected for evaluation including Acid Phosphatase, Alkaline Phosphatase, Albumin, ALT, Amylase, AST, Bicarbonate, Direct Bilirubin, Total Bilirubin, Calcium, Chloride, Creatinine Kinase, Creatinine, Gamma GT, Glucose, Inorganic Phosphate, Iron, LDH, Magnesium, Total Protein, Triglycerides, Urea, Uric Acid, Benzodiazepine, Cocaine, Opiate, Amphetamine, Methadone, THC, Cyclosporin, and Carbamazepine. These include the following analytical modes: endpoint, kinetic with linearity check, bichromatic endpoint, two-point kinetic, and non-linear calibration curve.

The data for precision, accuracy, linearity and drift demonstrate general agreement with levels that are comparable to other systems presently being

marketed commercially in the United States. The data demonstrate positive correlation and substantial equivalence.

The optional Vitalab ISE accessory for the determination of Sodium, Potassium, and Chloride is manufactured by AVL Scientific Corp. This unit is essentially equivalent to other ISE units marketed by AVL in the United States.

Vital Scientific NV, submits that the Vitalab Flexor System has clinically acceptable performance comparable to similar devices currently in commercial distribution. These data provide scientific evidence of equivalency for Vitalab Flexor System. The data indicates a positive correlation, and therefore, is substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Israel M. Stein, M.D.
.Managing Director
Vital Scientific
One Gateway Center, Suite 415
Newton, Massachusetts 02158

MAR 13 1998

Re: K973628
VITALAB FLEXOR Analyzer
Regulatory Class: II
Product Code: JJF, CDN, CEM, CGA, DJC, DKZ, JGS,
JXO, KLT, LAR, JRE
Dated: January 30, 1998
Received: February 2, 1998

Dear Dr. Stein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

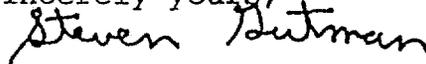
Page 2

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/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 (if known): K97 3628

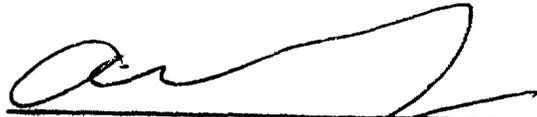
Device Name: VITALAB FLEXOR

Indications For Use:

This notification is for an *in vitro* diagnostic device, which is an automated chemistry analyzer, micro type, intended for clinical use in conjunction with certain materials to measure a variety of analytes, including applications in clinical chemistry, monitoring drugs of abuse and in therapeutic drug monitoring.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K973628

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

190