B. 510(k) SUMMARY

Amira Medical 510(k) Premarket Notification for The AtLast™ Control Solution

1. **Submitter's Name, Address, Telephone Number, and Contact Person**

Amira Medical
4742 Scotts Valley Road
Scotts Valley, CA 95066
Phone:(408) 440 5448
Facsimile: (408) 439-0907

Contact Person: Nina Peled, Ph.D., MBA
Vice President, Scientific Affairs

2. **Date Prepared: March 25, 1999**

3. **Name of Device and Name/Address of Sponsor**

Trade name: **The AtLast™ Control Solution**

Amira Medical
4742 Scotts Valley Road
Scotts Valley, CA 95066

4. **Classification Names:**

Single (specified) analyte controls (assayed and unassayed) (21 C.F.R. § 862.1660)

5. **Predicate Devices**

The Accu-Chek® Instant™ (K944459) Glucose Control (Accu-Chek, Roche Diagnostics, Indianapolis, IN.)

6. **Intended Use/Indications**

For use with the AtLast Blood Glucose System for quality control purposes to verify that the AtLast meter and test strips perform well together.

7. **Device Description**

The AtLast Glucose Control Solution is an aqueous control. The control is intended to be used with the AtLast Blood Glucose System (AtLast System, K982076) for quality control purposes by the end-user (diabetic consumer). The AtLast System is an over-the-counter

(OTC) combination blood sampler and glucose meter that provides blood glucose measurements on samples obtained from various body sites including the forearm, the upper arm, the thigh and the finger tip.

8. Principle of Operation

The AtLast control solutions are utilized as follows. Users are instructed to tilt the cap of the control packet until it breaks off. A drop of the control solution is then placed on a clean surface. The AtLast test strip is inserted into the AtLast meter and the meter in turned on. The tip of the AtLast test strip is then touched to the control solution to draw up the fluid into the AtLast test strip by capillary action and the meter performs the glucose assay. Results are displayed by digital readout of glucose in mg/dL just as would be done with the user's blood sample.

9. Data Demonstrating Substantial Equivalence

The AtLast Glucose Control solutions were evaluated via comprehensive precision studies. Each level of glucose control was assayed with three AtLast systems, in triplicate, over 20 days. This resulted in a total of 60 measurements per level, per meter. The data were analyzed according to NCCLS Document EP 5-T2, "Evaluation of Precision Performance of Clinical Chemistry Devices," 2nd Edition, Vol. 12, No. 4, and are expressed in terms of: within-run imprecision, and total imprecision.

The data indicate good performance for all glucose levels.

Conclusion:

The Studies demonstrate that the Amira Medical AtLast Control Solution is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 17 2000

Nina Peled, Ph.D., MBA
Vice President, Scientific Affairs
Amira Medical
4742 Scotts Valley Road
Scotts Valley California 95066

Re: K991075
Trade Name: The AtLast™ Control Solution
Regulatory Class: I
Product Code: JJX
Dated: March 30, 1999
Received: March 31, 1999

Dear Dr. Peled:

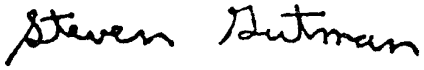
This letter corrects our substantially equivalent letter dated May 10, 1999 to change from prescription use to over-the-couter-use. We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket 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.

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 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 (IF KNOWS) : K991075

DEVICE NAME: ATLAST GLUCOSE CONTROL SOLUTION

INDICATIONS FOR USE:

An assayed control solution for use with the AtLast Blood Glucose System for quality control purposes to verify that the AtLast meter and test strips perform well together.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991075

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ✓
(Optional Format 1-2-96)