MAY 28 1999

Sienco, Inc.
4892 Van Gordon St. - Unit 203
Wheat Ridge, CO USA 80033
303/420-1148 303/420-2204(Fax)
800/432-1624

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K984141 .

(1) **Contact Person:** Barbara DeBiase, Director, Sienco Inc.
Summary Preparation Date: 1 November 1998

(2) **Device Trade Name:** gbACT+ Kit
Common Name: Activated Clotting Time (ACT) Test
Classification Name: Activate Whole Blood Clotting Time Test
Classification: Class II, 21 CFR 864.7140

(3) **Identification of predicate device to which substantial equivalence is being claimed:** SonACT Kit, 510(k) # K952560

(4) **and (5) Device Description and Intended Use:** The gbACT+ Kit is an in-vitro diagnostic product designed for use with the Sonoclot Coagulation & Platelet Function Analyzer System. Each kit contains glass bead cuvettes, probes and instructions for use. Current package sizes of 100 (#800-0412) and 24 (#800-0411) tests are available. The lidded pink cuvettes contain a controlled amount of the glass bead activator and a magnetic stir bar. A mason box is used for the kit package.

The gbACT+ test is an activated whole blood clotting time test. It may also be used with citrated whole blood or plasma. The gbACT+ Kit is intended for general purpose global hemostasis monitoring including: clot detection, fibrin formation, platelet function, and hyperfibrinolysis. The monitoring information is typically used for anticoagulant management at low to moderate heparin levels (1 to 2 units per ml), hypercoagulable and/or hypocoagulable screening, platelet function assessment, and hyperfibrinolysis screening.

(6) Technological Characteristic Comparison of the gbACT+ Kit to the standard SonACT Kit:

ITEM	gbACT+	STANDARD SONACT
Classification Name	Activated Whole Blood Clotting Time Test	Activated Whole Blood Clotting Time Test
IVD Reagent for Use With	Sonoclot Coagulation & Platelet Function Analyzer	Sonoclot Coagulation & Platelet Function Analyzer
Intended Use	General purpose global hemostasis monitoring, hypercoagulable and hyperfibrinolysis screening, platelet function assessment, anticoagulation management (low to moderate heparin levels)	General purpose global hemostasis monitoring, hypercoagulable and hyperfibrinolysis screening, platelet function assessment, anticoagulation management (low to high heparin levels)
Results Provided	Quantitative results for Activated Clotting Time (Onset /ACT Time). Qualitative and quantitative fibrin formation information (Clot RATE, Sonoclot Signature). Qualitative and quantitative platelet function information from Sonoclot Signature. Qualitative and quantitative hyperfibrinolysis information from Sonoclot Siganture.	Quantitative results for Activated Clotting Time (Onset/ACT Time). Qualitative and quantitative fibrin formation information (Clot RATE, Sonoclot Signature). Qualitative and quantitative platelet function information from Sonoclot Signature. Qualitative and quantitative hyperfibrinolysis information from Sonoclot Siganture.
Test Design	Pink plastic lidded cuvette containing contact activator (glass beads) and magnetic stir bar	Colorless plastic lidded cuvette containing contact activator (celite) and magnetic stir bar
Kit Contents	Cuvettes, probes and instructions for use	Cuvettes, probes and instructions for use
Quality Control	Reference Plasma Quality Control Kit, Sienco part #900-1318	Reference Plasma Quality Control Kit, Sienco part #900-1318

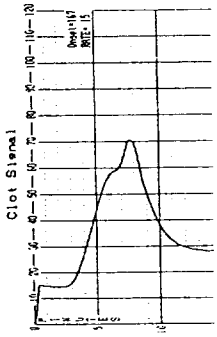
(7) **Performance Comparison of the gbACT+ Kit to the standard SonACT Kit:** Expected values for the gbACT+ Kit and the standard SonACT Kit are provided in the tables below. Actual Sonoclot Signatures from two normals using the gbACT+ test and the standard SonACT test are also included.

gbACT+ Typical Results and Examples

gbACT+ Test (#800-0411, 800-0412) Native Whole Blood - Normal Population, No Heparin	
Result	**Normal Range**
ACT/Onset	125 - 220 seconds
Clot RATE	10-45 Clot Signal Units / minute
Time to Peak	<20 minutes

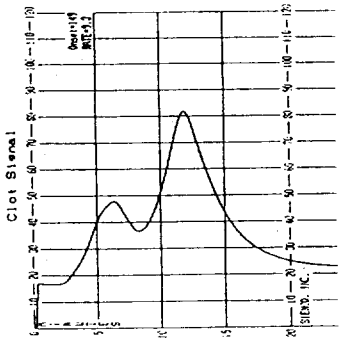
Normal A: Native Whole Blood: gbACT+

Onset/ACT: 167
ClotRATE: 15
Time to Peak: 8



Normal B: Native Whole Blood: gbACT+

Onset/ACT: 149
ClotRATE: 9
Time to Peak: 12

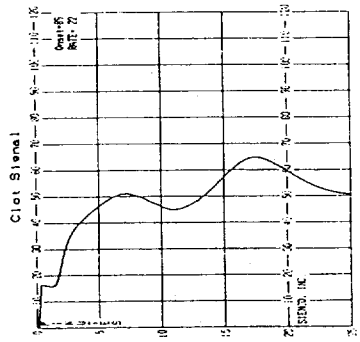


SonACT Typical Results and Examples for Comparison

Standard SonACT Test (#800-0432, #800-0431) Native Whole Blood - Normal Population, No Heparin	
Result	**Normal Range**
ACT/Onset	85-145 seconds
Clot RATE	15-45 Clot Signal Units / minute
Time to Peak	<30 minutes

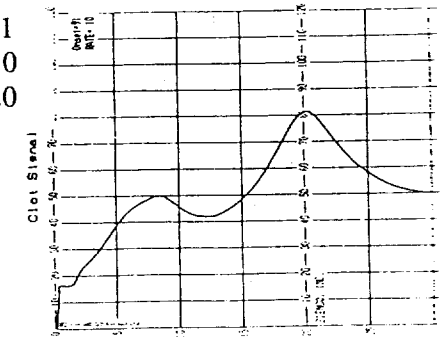
Normal A: Native Whole Blood: SonACT

Onset/ACT: 89
ClotRATE: 22
Time to Peak: 17



Normal B: Native Whole Blood: SonACT

Onset/ACT: 91
ClotRATE: 10
Time to Peak: 20



Barbara DeBiase 16 June 1998
Barbara DeBiase, Director

044

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 28 1999

Barbara Debiase
SIENCO, INC.
4892 Van Gordon Street
Unit 203
Wheatridge, CO 80033

Re: K984141
Trade Name: gbACT + Kit
Regulatory Class: II
Product Code: JBP
Dated: May 11, 1999
Received: May 12, 1999

Dear Ms. Debiase:

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.

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/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

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): K984141

Device Name: gbACT+ Kit

Indications For Use:

The gbACT+ Kit is an in-vitro diagnostic product designed for use with the Sonoclot Coagulation & Platelet Function Analyzer System. The gbACT+ test is an activated whole blood clotting time test. It may also be used with citrated whole blood or plasma. The gbACT+ Kit is intended for general purpose global hemostasis monitoring including: clot detection, fibrin formation, platelet function, and hyperfibrinolysis. The monitoring information is typically used for anticoagulant management at low to moderate heparin levels (0 to 2 units per ml), hypercoagulable and/or hypocoagulable screening, platelet function assessment, and hyperfibrinolysis screening.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maseri

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984141

Prescription Use ✓ OR **Over-The-Counter Use** ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)