

SIENCO, Inc.

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K952560

510(k) SUMMARY

SEP - 5 1995

- 1) **Contact Person:** Jon Henderson, Vice President, Sienco Inc.
Summary Preparation Date: May 22, 1995
- 2) **Device Trade Name:** Sonoclot® Coagulation & Platelet Function Analyzer
Common Name: Coagulation Analyzer
Classification Name: Multipurpose system for in vitro coagulation studies
Classification: Class II, Classification Number 81JPA, 21 CFR 864.5425.
- 3) **Identification of predicate device to which substantial equivalence is being claimed:** Original Sonoclot Analyzer marketed prior to May 28, 1976.
- 4) and 5) **Device Description and Intended Use:** The Sonoclot Coagulation & Platelet Function Analyzer is an instrument for the in vitro measuring of coagulation and platelet function. The Sonoclot Analyzer performs in vitro whole blood and plasma analyses.

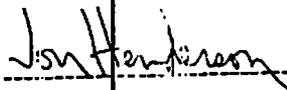
The Sonoclot Analyzer rapidly provides accurate information on the entire hemostasis process including coagulation, fibrin gel formation, clot retraction (platelet function) and fibrinolysis. The Sonoclot Analyzer generates both a qualitative graph, known as the Sonoclot Signature, and the quantitative results on the clot formation time and the rate of fibrin polymerization for identifying numerous coagulopathies including platelet dysfunction, factor deficiencies, anticoagulant effect, hypercoagulable tendencies and hyperfibrinolysis.

The detection mechanism within the Sonoclot Analyzer responds to mechanical changes that occur within the blood sample. This mechanism consists of a tubular probe that oscillates up and down within a blood sample. The electronic drive and detection circuitry senses the resistance to motion that the probe encounters as the blood sample progresses through the various stages of hemostasis. The resulting analog electronic signal is processed by a microcomputer within the Sonoclot Analyzer and is reported as the Clot Signal. The Clot Signal is printed as a graph on the thermal printer.

The materials used to construct the Sonoclot Analyzer and its physical dimensions are covered in this summary under item (6).

- 6) **Comparison of the current to the original Sonoclot:** See Table 1 attached. Testing additionally has been completed to demonstrate that the current Sonoclot Analyzer is equivalent to the original Sonoclot Analyzer. Several different reference viscosity fluids, plasma and blood were run side by side on three current and three original analyzers. No difference in performance was observed between the automatically calculated results obtained on the current analyzer and the manually calculated results obtained on the original analyzer. Moreover, the current analyzer eliminates the possibility of the user performing incorrect calculations.

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.



Jon Henderson
Vice President

22 MAY 95

Date

Sienco, Inc.
Sonoclot Coagulation & Platelet Function Analyzer
510(K) NOTIFICATION

TABLE I - Table showing the equivalence of the current to the original SONOCLOT Analyzer

ITEM	Current Sonoclot	Original Sonoclot
USE	The current Sonoclot Coagulation & Platelet Function Analyzer is an instrument used for measuring coagulation and platelet function. It provides rapid, accurate information on the entire hemostasis process including coagulation, fibrin gel formation, clot retraction (platelet function) and fibrinolysis. The current Sonoclot requires less user intervention and many features have been automated and standardized.	The original Sonoclot Coagulation & Platelet Function Analyzer was an instrument used for measuring coagulation and platelet function. It provided accurate information on the entire hemostasis process including coagulation, fibrin gel formation, clot retraction (platelet function) and fibrinolysis.
RESULTS	Provides quantitative results for the clot formation time SonACT (Sonoclot Activated Clotting Time) and the rate of fibrin polymerization (Clot Rate). Provides qualitative graph known of the Sonoclot Signature.	Provided quantitative results for the clot formation time SonACT (Sonoclot Activated Clotting Time) and the rate of fibrin polymerization (Clot Rate). Provided qualitative graph known of the Sonoclot Signature.
DESIGN / MATERIALS	Side panels are made from machined aluminum and painted. Bottom, top, front and rear panels are stamped stainless sheet metal. Front angled control panel is made from etched zinc. The platen (heater block) is made from anodized aluminum. The transducer head and hinge assembly is machined anodized aluminum. The transducer head assembly hinge pin is machined Dupont delrin®.	Side panels were made from machined aluminum and painted. Bottom, top, front and rear panels were stamped stainless sheet metal. Front angled control panel was made from etched zinc. The platen (heater block) was made from anodized aluminum. The transducer head and hinge assembly was machined anodized aluminum. The transducer head assembly hinge pin was machined Dupont delrin®.
VISUAL IDENTITY	Brushed stainless steel, black side panels and clear anodized aluminum. Front panel graphics and text done in orange and black paint.	Brushed stainless steel, black side panels and clear anodized aluminum. Front panel graphics and text done in orange and black paint.
POWER	100 to 130Vac or 210 to 260Vac user selectable 55 watts The current power requirements have been narrowed to fall within the original ranges.	90 to 135Vac or 180 to 270Vac factory option only 55 watts



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 5 1995

Mr. Jon Henderson
• Vice President
Sienco, Inc.
557 Unit C Burbank Street
Broomfield, Colorado 80020

Re: K952560
Sonoclot® Coagulation & Platelet Function Analyzer
Regulatory Class: II
Product Code: JPA
Dated: May 22, 1995
Received: June 2, 1995

Dear Mr. Henderson:

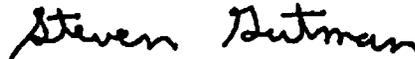
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have 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 (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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-320) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



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

