OCT 20 2011 K110432

510(k) Summary for VisuCon-F Frozen Coag Screen N (Summary of Safety and Effectiveness)

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.

Submitted By:	Affinity Biologicals Inc. 1395 Sandhill Drive Ancaster, ON Canada, L9G 4V5 Phone: 905-304-9896 Fax: 905-304-9897
Contact Person:	Denise Foulon, Scientific Director Phone: 905-304-9896 Fax: 905-304-9897
Summary Prepared:	October 11, 2011
Name of the Device:	VisuCon-F Frozen Coag Screen N Common Name: Normal Control Plasma
Classification of Device:	Class II 21 CFR 864.5425 Subpart H, Hematology Kits and Packages Product Code: GGN
Predicate Device:	HemosIL Routine Control Level 1, K082859 Instrumentation Laboratory
Device Description:	The VisuCon-F Frozen Coag Screen N is a pool of normal citrated human plasma collected from a minimum of 20 donors, buffered with 0.02 M HEPES buffer, dispensed and rapidly frozen.
Device Intended Use:	The VisuCon-F Frozen Coag Screen N plasma is an assayed normal control plasma intended for use in the quality control of quantitative coagulation assays, including Prothrombin Time (PT), Activated partial thromboplastin time (APTT) and fibrinogen, in the normal range. The VisuCon-F Frozen Coag Screen N plasma may be used with mechanical and photo-optical coagulation instruments in conjunction with appropriate commercial reagents.

Comparison to Predicate Device:
A technical comparison of the proposed device and the predicate device is illustrated in the following table:

	VisuCon-F Frozen Coag Screen N (Proposed Device)	**HemosIL Routine Control Level 1, (Predicate Device)**
Intended Use	For the quality control of coagulation assays in the normal range	For the quality control of coagulation assays in the normal range
Analytes	Prothrombin time (PT), Activated partial thromboplastin time (APTT), Fibrinogen	Prothrombin time (PT), Activated partial thromboplastin time (APTT), Fibrinogen
Matrix	Citrated human plasma	Citrated human plasma
Format	Frozen	Lyophilized
Open-Vial Stability	8 hours at 2-8°C or on-board coagulation instrument (15-22°C)	8 hours at 2-8°C

Conclusion: The VisuCon-F Frozen Coag Screen N is substantially equivalent to its predicate device, HemosIL Routine Control Level 1, based on similar intended use, product matrix and stability. To our knowledge, any differences, such as product format (frozen versus lyophilized), do not affect the safety and effectiveness of the proposed device.

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510(k) Summary for VisuCon-F Frozen Coag Screen ABN
(Summary of Safety and Effectiveness)

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.

Submitted By:

Affinity Biologicals Inc.
1395 Sandhill Drive
Ancaster, ON
Canada, L9G 4V5
Phone: 905-304-9896
Fax: 905-304-9897

Contact Person:

Denise Foulon, Scientific Director
Phone: 905-304-9896
Fax: 905-304-9897

Summary Prepared: October 11, 2011

Name of the Device:

VisuCon-F Frozen Coag Screen ABN
Common Name: Abnormal Control Plasma

Classification of Device:

Class II
21 CFR 864.5425
Subpart H, Hematology Kits and Packages
Product Code: GGN

Predicate Device:

HemosIL Routine Control Level 2, K082859
Instrumentation Laboratory

Device Description:

The VisuCon-F Frozen Coag Screen ABN is a pool of normal citrated human plasma collected from a minimum of 20 donors, diluted to defined concentrations, buffered with 0.02 M HEPES buffer, dispensed and rapidly frozen.

Device Intended Use:

The VisuCon-F Frozen Coag Screen ABN plasma is an assayed abnormal control plasma intended for use in the quality control of quantitative coagulation assays, including Prothrombin Time (PT) and Activated partial thromboplastin time (APTT), in the mid-level abnormal range. The VisuCon-F Frozen Coag Screen ABN plasma may be used with mechanical and photo-optical coagulation instruments in conjunction with appropriate commercial reagents.

Comparison to Predicate Device:
A technical comparison of the proposed device and the predicate device is illustrated in the following table:

	VisuCon-F Frozen Coag Screen ABN (Proposed Device)	**HemosIL Routine Control Level 2, (Predicate Device)**
Intended Use	For the quality control of coagulation assays in the mid-level abnormal range	For the quality control of coagulation assays in the low abnormal range
Analytes	Prothrombin time (PT), Activated partial thromboplastin time (APTT),	Prothrombin time (PT), Activated partial thromboplastin time (APTT)
Matrix	Citrated human plasma	Citrated human plasma
Format	Frozen	Lyophilized
Open-Vial Stability	8 hours at 2-8°C or on-board coagulation instrument (15 - 22°C)	8 hours at 2-8°C

Conclusion: The VisuCon-F Frozen Coag Screen ABN is substantially equivalent to the predicate device, HemosIL Routine Control Level 2, based on similar intended use, product matrix and stability. To our knowledge, any differences, such as product format (frozen versus lyophilized), do not affect the safety and effectiveness of the proposed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Affinity Biologicals Inc.
c/o Ms. Denise Foulon
1395 Sandhill Dr.
Ancaster, Ontario
Canada L9G 4V5

OCT 20 2011

Re: k110432
Trade/Device Name: VisuCon-F Frozen Coag Screen N
VisuCon-F Frozen Coag Screen ABN
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: GGN
Dated: October 11, 2011
Received: October 12, 2011

Dear Ms. Foulon,

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Reena Philip

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K110432

Device Name: VisuCon-F Frozen Coag Screen N

Indications for Use:

The VisuCon-F Frozen Coag Screen N plasma is an assayed normal control plasma intended for use in the quality control of quantitative coagulation assays, including Prothrombin Time (PT), Activated partial thromboplastin time (APTT) and fibrinogen, in the normal range. The VisuCon-F Frozen Coag Screen N plasma may be used with mechanical and photo-optical coagulation instruments in conjunction with appropriate commercial reagents.

Prescription Use √ (Part 21 CFR 801 Subpart D) **AND/OR** Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Reena Philip

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K K110432

Indications For Use Statement

510(k) Number (if known): K110432

Device Name: VisuCon-F Frozen Coag Screen ABN

Indications for Use:

The VisuCon-F Frozen Coag Screen ABN plasma is an assayed abnormal control plasma intended for use in the quality control of quantitative coagulation assays, including Prothrombin Time (PT) and Activated partial thromboplastin time (APTT), in the mid-level abnormal range. The VisuCon-F Frozen Coag Screen ABN plasma may be used with mechanical and photo-optical coagulation instruments in conjunction with appropriate commercial reagents.

Prescription Use √ (Part 21 CFR 801 Subpart D) **AND/OR** Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Reena Philip

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K k110432