DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

March 6, 2016

Affinity Biologicals Inc.
Denise Foulon
Scientific Director
1348 Sandhill Drive
Ancaster, ON
Canada, L9G 4V5

Re: K150144
Trade/Device Name: VisuCon-F Low Fibrinogen Control Plasma
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: GGN
Dated: February 1, 2016
Received: February 2, 2016

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150144

Device Name
VisuCon-F Low Fibrinogen Control Plasma

Indications for Use *(Describe)*
The VisuCon-F Low Fibrinogen Control Plasma is an assayed control plasma prepared from de-fibrinated human plasma intended for use in the quality control of quantitative fibrinogen assays in the low abnormal range. The VisuCon-F Low Fibrinogen Control Plasma may be used with mechanical instruments in conjunction with appropriate commercial reagents for determining fibrinogen levels in plasma by the clotting method of Clauss. This plasma is intended "For In Vitro Diagnostic Use".

The intended users of the VisuCon-F Low Fibrinogen Control Plasma are trained laboratory personnel working in clinical laboratories.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary for VisuCon-F Low Fibrinogen Control Plasma (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:

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Contact Person:

Denise Foulon, Scientific Director
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Summary Prepared: January 29, 2016

Name of the Device:

VisuCon-F Low Fibrinogen Control Plasma
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:

Cryocheck Low Fibrinogen Control Plasma
Precison Biologic Inc.

Device Description:

The VisuCon-F Low Fibrinogen Control plasma is a pool of de-fibrinated citrated human plasma buffered with 0.02 M HEPES buffer, dispensed and rapidly frozen.

Device Intended Use:

The VisuCon-F Low Fibrinogen Control Plasma is an assayed control plasma prepared from de-fibrinated human plasma intended for use in the quality control of quantitative fibrinogen assays in the low abnormal range. The VisuCon-F Low Fibrinogen Control Plasma may be used with mechanical instruments in conjunction with appropriate commercial reagents for determining fibrinogen levels in plasma by the clotting method of Clauss. This plasma is intended “For *In Vitro* Diagnostic Use”.

The intended users of the VisuCon-F Low Fibrinogen Control Plasma are trained laboratory personnel working in clinical laboratories.

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

	VisuCon-F Low Fibrinogen Control Plasma (Proposed Device)	**Cryocheck Low Fibrinogen Control Plasma (Predicate Device)**
Intended Use	An assayed control plasma prepared from de-fibrinated human plasma intended for use in the quality control of quantitative fibrinogen assays in the low abnormal range	Recommended for use as an abnormal control in quantitative fibrinogen assays
Analytes	Fibrinogen	Fibrinogen
Matrix	Citrated human plasma	Citrated human plasma
Format	Frozen	Frozen
Open-Vial Stability	72 hours at 2-8°C or 8 hours on-board instrument (19-22°C)	72 hours at 2-8°C
Precision (% Coefficient of Variation (CV))	Within Run = 3.15% Between Day = 0.54% Between Run = 0% Within Device = 8.44%	2.8 – 3.7% (n = 36)

Conclusion: The VisuCon-F Low Fibrinogen Control plasma is substantially equivalent to its predicate device, Cryocheck Low Fibrinogen Control plasma, based on similar intended use, product matrix, stability and performance characteristics (precision).