STRATEC Biomedical UK Limited
Attention: Mr. Eric Waltz
STRATEC Biomedical USA, Inc.
98 Main Street, Suite 205
Southington, CT 06489

October 30, 2017

Re:	BK160071
Device Name:	Aurora Enterprise
Regulation Name:	Blood Establishment Computer Software And Accessories
Regulatory Class:	Unclassified
Product Code:	MMH
Dated:	October 24, 2017
Received:	October 24, 2017

Dear Mr. Waltz:

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 a legally marketed predicate device 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 (the 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 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 Part 801); 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), 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 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Orieji Illoh, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosure
Indications For Use

Indications for Use

510(k) Number: BK160071

Device Name: Aurora Enterprise

Indications for Use:

Aurora Enterprise is a computer software product for use within Blood Establishments and Clinical Diagnostic Laboratories which enables communication between Laboratory Information Systems and Laboratory Instrumentation. The software product is designed to capture and collate data provided by laboratory instrumentation, where the instrumentation is capable of performing its own data processing, having qualified the data and converted the 'raw values' into interpreted results. The software collects data of assays from instruments, which allow operators to track patient samples and link them to the appropriate test results. The software collates the results of testing, and formats output files that can be sent to a Laboratory Information System (LIS). In addition, rules may be configured to determine a final result outcome prior to formatting output files for export to an LIS. The software allows for manual entry of results. Typical tests would include those that are used to screen blood donations (whole blood or plasma) as a pre-requisite to transfusion such as viral markers tested by NAT/PCRand Immunoassay. The software has the capability to send worklists to instruments from orders it receives from an LIS, or manually entered, but takes no control over any instrument operation.

Aurora Enterprise is intended for use by Blood Establishment and Clinical Diagnostic laboratory personnel who are trained in its operation.

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

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

Concurrence of CBER, Office of Blood Research and Review

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Division Sign-Off, Office of Blood Research and Review