



Haemonetics Corporation Software Solutions
Attention: Ms. Allyson Parks
4925 Robert J. Matthews Parkway
Suite 100
Eldorado Hills, CA 95762

Re: BK150330
Trade Name: NextGen 3.0.0
Regulation Name: Stand Alone Blood Bank Software
Regulatory Class: Unclassified
Product Code: MMH
Dated: February 29, 2016
Received: February 29, 2016

Dear Ms. Parks:

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 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 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,

Richard J. Davey, 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: BK150330

Device Name: NextGen 3.0.0

Indications for Use:

NexGen is designed to undertake donation center operations, including but not limited to recruitment of donors, screening of donors for suitability, immunizations, blood product collection processing, crossmatching and providing lookback capabilities. NexGen manages donor information and allows multiple methods to identify donors, including biometrics such as fingerprints. NexGen is also designed to manage donor and product testing, labeling, barcode scanning, equipment, supplies, quality assurance, inventory, shipping, and product release. The NexGen questionnaire and phlebotomy functionalities can operate stand-alone. NexGen can interface with:

- External donor management systems
- Cross donation check systems
- Apheresis devices
- Screening test instruments
- Test lab systems
- Deferral registry systems
- Other BECS systems

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CBER, Office of Blood Research and Review

Division Sign-Off
Office of Blood Research and Review