



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 22, 2016

Streck, Inc.
Ms. Deborah Kipp
Regulatory Affairs Manager
7002 South 109th Street
LaVista, NE 68128

Re: K160586
Trade/Device Name: XN-L CHECKTM
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: Class II
Product Code: JPK
Dated: December 15, 2016
Received: December 16, 2016

Dear Ms. Kipp:

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 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,

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

Indications for Use

510(k) Number (if known)

Device Name

XN-L CHECK

Indications for Use (Describe)

XN-L CHECK is used for control and calibration verification of Sysmex XN-L analyzers. It is not, however, intended for actual calibration of this analyzer.

Assayed parameters include:

RBC ($10^6/\mu\text{L}$), HGB (g/dL), HCT (%), MCV (fL), MCH (pg), MCHC (g/dL), PLT ($10^3/\mu\text{L}$), RDW-SD (fL), RDW-CV (%), MPV (fL), WBC ($10^3/\mu\text{L}$), NEUT (%), LYMPH (%), MONO (%), EO (%), BASO (%), IG (%), NEUT# ($10^3/\mu\text{L}$), LYMPH# ($10^3/\mu\text{L}$), MONO# ($10^3/\mu\text{L}$), EO# ($10^3/\mu\text{L}$), BASO# ($10^3/\mu\text{L}$), IG# ($10^3/\mu\text{L}$), RET# ($10^6/\mu\text{L}$), RET%, IRF%, RET-He (pg).

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

510(k) Submitter: Streck
7002 South 109th Street
La Vista, NE 68128

Official Correspondent: Deborah Kipp, Regulatory Affairs Manager
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Date Prepared: Revised October 19, 2016

Names

Trade Name: XN-L CHECK™
Common Name: Assayed Hematology Control
Classification Name: Hematology quality control mixture (864.8625)
Product Code: JPK
Panel: Hematology

Predicate Device:

XN CHECK™ (K141964)

Intended Use:

XN-L CHECK is used for control and calibration verification of Sysmex XN-L analyzers. It is not, however, intended for actual calibration of this analyzer. Assayed parameters include:

RBC ($10^6/\mu\text{L}$), HGB (g/dL), HCT (%), MCV (fL), MCH (pg), MCHC (g/dL), PLT ($10^3/\mu\text{L}$), RDW-SD (fL), RDW-CV (%), MPV (fL), WBC ($10^3/\mu\text{L}$), NEUT (%), LYMPH (%), MONO (%), EO (%), BASO (%), IG (%), NEUT# ($10^3/\mu\text{L}$), LYMPH# ($10^3/\mu\text{L}$), MONO# ($10^3/\mu\text{L}$), EO# ($10^3/\mu\text{L}$), BASO# ($10^3/\mu\text{L}$), IG# ($10^3/\mu\text{L}$), RET# ($10^6/\mu\text{L}$), RET%, IRF%, RET-He (pg).

Description:

XN-L CHECK™ is an in-vitro diagnostic, three level (Levels 1, 2, and 3) hematology product that contains the following: stabilized red blood cell component(s), stabilized white blood cell component(s), and stabilized platelet component(s) in a preservative medium. The product is packaged in polypropylene plastic vials with screw caps with a 3 ml fill. The vials will be packaged in (4) welled vacuum formed clamshell container with the Instructions for Use (IFU) / assay sheet. Product storage conditions are 2 - 8° C.

Comparison to Predicate Device:

	XN-CHECK (K141964)- Predicate Device	XN-L CHECK™-Candidate Device	Same or Differences
Intended Use Statement	XN CHECK is used for control and calibration verification of Sysmex XN series (XN-10, XN-11, XN-20, XN-21) analyzers. It is not, however, intended for actual calibration of these analyzers. Assayed parameters include: RBC($10^6/\mu\text{L}$), HGB(g/dL), HCT(%), MCV(fL), MCH(pg), MCHC(g/dL), PLT($10^3/\mu\text{L}$), PLT-F($10^3/\mu\text{L}$), RDW-SD(fL), RDW-CV(%), MPV(fL), WBC($10^3/\mu\text{L}$), NEUT(%), LYMPH(%), MONO(%), EO(%), BASO(%), IG(%), NEUT#($10^3/\mu\text{L}$), LYMPH#($10^3/\mu\text{L}$), MONO#($10^3/\mu\text{L}$), EO#($10^3/\mu\text{L}$), BASO#($10^3/\mu\text{L}$), IG#($10^3/\mu\text{L}$), IPF(%), IPF #($10^3/\mu\text{L}$) RET#($10^6/\mu\text{L}$), RET%, IRF%, RET-HE(pg), NRBC#($10^3/\mu\text{L}$), NRBC% (/100 WBC)	XN-L CHECK is used for control and calibration verification of Sysmex XN-L analyzers. It is not, however, intended for actual calibration of this analyzer. Assayed parameters include: RBC ($10^6/\mu\text{L}$), HGB (g/dL), HCT (%), MCV (fL), MCH (pg), MCHC (g/dL), PLT ($10^3/\mu\text{L}$), RDW-SD (fL), RDW-CV (%), MPV (fL), WBC ($10^3/\mu\text{L}$), NEUT (%), LYMPH (%), MONO (%), EO (%), BASO (%), IG (%), NEUT# ($10^3/\mu\text{L}$), LYMPH# ($10^3/\mu\text{L}$), MONO# ($10^3/\mu\text{L}$), EO# ($10^3/\mu\text{L}$), BASO# ($10^3/\mu\text{L}$), IG# ($10^3/\mu\text{L}$), RET# ($10^6/\mu\text{L}$), RET%, IRF%, RET-He (pg).	Product is a control for XN-L analyzer. The following measurands are not available on XN-L CHECK or the XN-L analyzer: IPF(#) IPF(%) NRBC#($10^3/\mu\text{L}$) NRBC%(/100WBC)
Open Vial Stability	7 days	15 days	Increased Open Vial Stability to 15 days
Closed Vial Stability	84 days	100 days	Increased Closed Vial Stability to 100 days
Reagents	XN CHECK contains the following: stabilized red blood cell component(s), stabilized white blood cell component(s), stabilized platelet component(s), and stabilized nucleated red blood cell component(s) in a preservative medium.	XN-L CHECK contains the following: stabilized red blood cell component(s), stabilized white blood cell component(s), and stabilized platelet component(s) in a preservative medium.	Removal of nucleated red blood cell component(s)
Storage Conditions	2 - 8° C	2 - 8° C	Same

Discussion of Tests and Test Results:

To substantiate the product performance claims for XN-L CHECK, Streck collected product performance data for the following studies: Multi-Site Precision Study, Single-Site Precision Study, Open-Vial Stability and Closed-Vial Stability. The resultant data set established that XN-L CHECK is safe and effective for its intended use and that the product is stable for the entire product dating. The product fulfills its intended use as instructed in the Instructions for Use.

Conclusions Drawn From Tests:

Study results show XN-L CHECK to be consistently reproducible, substantially equivalent to the predicate products, and stable for the entire product dating. XN-L CHECK is a safe and effective product, which fulfills its intended use when used as instructed in the Instructions for Use.