.RTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 9, 2014

North American Science Assoc., Inc.
Ms. Julie Wheeler
General Manager
6750 Wales Rd.
Northwood, Ohio 43619

Re: K141244
Trade/Device Name: NAMSA Biological Indicator Spore Strips
Regulation Number: 21 CFR 880.2800
Regulation Name: Indicator/Biological Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: August 8, 2014
Received: August 12, 2014

Dear Ms. Wheeler,

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" (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 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,

Tejashri Purohit-Sheth, M.D.

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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)*
K141244

Device Name
NAMSA Biological Indicator Spore Strip

Indications for Use *(Describe)*
The NAMSA Biological Indicator Spore Strip (single species Geobacillus stearothermophilus ATCC® 7953, product code STS-05R, or dual species Geobacillus stearothermophilus ATCC® 7953 and Bacillus atrophaeus ATCC® 9372, product code STNS-65R) is intended for use in testing the efficacy of chemiclave sterilization.

Performance characteristics are established for exposure at 132°C for 20 minutes in a MDT Harvey Chemiclave model EC5500 chemiclave sterilizer. Vapo-Steril Solution is the sterilant utilized in the MDT Harvey Chemiclave sterilizer. The solution was cleared under 510(k) number K984270. The validation load used for evaluation of the device performance characteristics consisted of stainless steel dental instruments in a wrapped tray with a mass of 1 kg.

A reduced incubation time of 72 hours for chemiclave sterilization at 132°C has been validated when the Biological Indicator Spore Strips are used in conjunction with Tryptic Soy Broth (TSB) modified with Bromocresol Purple and incubated at 58° - 62°C.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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Prepared on: April 4, 2014

Device Trade Name: NAMSA Biological Indicator Spore Strips

Common Name: Indicator/Biological Sterilization Process Indicator

Classification Name: Class II Medical Device, FDA Product Code FRC, General Hospital (21 CFR 880.2800)

Predicate Device: (Legally Marketed) Raven Bacterial Spore Strips

Predicate Device 510(k) Numbers: K912796, K020026 and K050591

Description: The Biological Indicator Spore Strips are typically used in a dental office but may be used by other small healthcare offices which utilize chemiclave processes to sterilize instruments. The spore strips are utilized to verify the chemiclave exposures were effective at killing the *Geobacillus stearothermophilus* bacterial spores present on the strips in high volume.

Modification to K113221 are to include chemiclave sterilization at 132℃ for 20 minutes in a Harvey model EC5500. The predicate device was not specific to sterilizer type or model number but rather is legally marketed for use in monitoring the chemiclave process. Specificity of the chemiclave model in no way affects the safety or effectiveness of the device.

NAMSA Biological Indicator Spore Strips are easy to use; simply place the spore strips in the most difficult area to sterilize and process the load as normal. After exposure, remove the spore strips and aseptically transfer to growth medium and incubated. After incubation if no signs of bacterial growth are present, the sterilization cycle was effect.

The spore strips may be aseptically transferred to standard media such as Tryptic Soy Broth (TSB) and incubated for a minimum of 7 days. Growth will be indicated by the presence of turbidity. Conversely, the strips may be cultured using TSB which has been modified with a pH indicator (Bromocresol Purple) for a reduced incubation time of 72 hours. Growth will be indicated by a change in color of the media from purple to yellow and/or presence of turbidity.

Biological Indicator Spore Strips consist of a 1.25" x 0.25" filter paper strip which has been inoculated with either single species (*Geobacillus stearothermophilus* ATCC® 7953 at a population level of 10^5 per strip), or dual species (*Geobacillus stearothermophilus* ATCC® 7953 at a population level of 10^5 and *Bacillus atrophaeus* ATCC® 9372 at a population level of 10^6 per strip). The spore strips are individually packaged in a 30# glassine pouch.

Intended Use:

The NAMSA Biological Indicator Spore Strip (single species *Geobacillus stearothermophilus* ATCC® 7953, product code STS-05R, or dual species *Geobacillus stearothermophilus* ATCC® 7953 and *Bacillus atrophaeus* ATCC® 9372, product code STNS-65R) is intended for use in testing the efficacy of chemiclave sterilization.

Performance characteristics are established for exposure at 132°C for 20 minutes in a MDT Harvey Chemiclave model EC5500 chemiclave sterilizer. Vapo-Steril Solution is the sterilant utilized in the MDT Harvey Chemiclave sterilizer. The solution was FDA cleared under 510(k) number K984270. The validation load used for evaluation of the device performance characteristics consisted of stainless steel dental instruments in a wrapped tray with a mass of 1 kg.

A reduced incubation time of 72 hours for chemiclave sterilization at 132°C has been validated when the Biological Indicator Spore Strips are used in conjunction with Tryptic Soy Broth (TSB) modified with Bromocresol Purple and incubated at 58° - 62°C.

Summary of Technological Characteristics:

The NAMSA Biological Indicator Spore Strip has the following similarities related to the technological characteristics of those legally marketed under 510(k) numbers K912796, K020026 and K050591:

Technological Characteristic	**New Device**	**Predicate Device**
	NAMSA Spore Strip	**Raven Bacterial Spore Strip**
Product Type	Biological Indicator	Biological Indicator
Intended Use	Chemiclave 132°C for 20 minutes, Harvey Model EC5500	Chemiclave at 132°C
Design/Materials		
Construction	Paper spore strip in glassine	Paper spore strip in glassine
Organism	*G. stearothermophilus*, ATCC® 7953	*G. stearothermophilus*, ATCC® 7953

Viable Spore Population	10^5/strip	10^5/strip
Certified Resistance Characteristics	Dvalue at 132℃: 1.0 to 3.0 Minutes Survival – Kill Windows at 132℃: 5 minute Survival, 15 Minute Kill	Survival – Kill Windows at 132℃: 5 minute Survival, 15 Minute Kill
Incubation Temperature	60°±2℃	60°±2℃
Readout Time in Modified Culture Medium (TSB with Bromocresol purple)	72 hours	72 hours
Shelf Life	18 Months	Minimum of 18 Months

The technological characteristics of the NAMSA BI spore strip are very similar to those of the predicate device in terms of design, materials, performance and principles of operation. The NAMSA BI spore strips have a more specific intended use by inclusion of the specific cycle and conditions; along with more defined resistance characteristics through a certified Dvalue associated with the specific intended use conditions.

Description of Testing:

In accordance with FDA recognized consensus standards and guidance documents applicable for chemiclave sterilization processes and based on the label claims of the predicate device, the following tests were performed to verify the performance of NAMSA Biological Indicator Spore Strip was substantially equivalent to the predicate device.

- Survival-Kill Window
  - The certified chemiclave resistance characteristics of the predicate device, survival time of 5 minutes and kill time of 15 minutes, was verified in conjunction with NAMSA's device to demonstrate equivalence.
- Population
  - NAMSA's Biological Indicator Spore Strips were evaluated to confirm equivalent population levels to the predicate device
- Readout Time
  - NAMSA's Biological Indicator Spore Strips were evaluated to confirm equivalent reduced incubation times to the predicate device

The following studies were performed to characterize the performance of NAMSA Biological Indicator Spore Strips for use in the stated chemiclave sterilization cycle:

- Resistance Characterization
  - Chemiclave Dvalue Determination at 124℃,132℃, 140℃
    Dvalues at each of the temperatures were determined using the Fraction Negative Method. NAMSA determined that the temperature range can vary from 124° - 140℃ in a standard chemiclave sterilizer when ran at the standard 132℃ cycle for 20 minutes.

  - Chemiclave Dvalue Verifications at 124℃,132℃, 140℃ Using Expired Vapo-Steril Solution
    To ensure that the resistance characteristics of NAMSA's device were addressed for the Vapo-Steril solution at the full extent of the Vapo-Steril solution's claimed shelf life, NAMSA evaluated the Dvalues for three lots of the device over the full temperature range at the end of the shelf life the Vapo-Steril solution.

- Verification of Survival-Kill Windows at End of Device Shelf Life
  The certified chemiclave resistance characteristics of the predicate device, survival time of 5 minutes and kill time of 15 minutes, were verified with NAMSA's device at the end of the shelf life to demonstrate the device performs as expected beyond the end of the shelf life.

- Load/Chamber Evaluation Studies
  - Claimed Sterilization Cycles
    To verify that the sterilization load would not negatively influence the effective sterilization chamber conditions and performance of the device, NAMSA conducted a study to verify the performance of the subject device in a full chamber. The validation load used for evaluation of the device performance characteristics consisted of stainless steel dental instruments in a wrapped tray with a mass of 1 kg.

  - Quantitative Determination of the Pre-Exposure Phase Lethality of the Chemiclave Process
    The study quantified the number of spores killed prior to initiation of the exposure phase (pre exposure) across the possible range of load conditions and temperature extremes.

- Carrier and Primary Packaging Material Evaluation
  The suitability of the carrier and primary packaging materials for the intended sterilization processes was determined through evaluation of the inhibitory properties of the materials on growth of *Geobacillus stearothermophilus* after sterilization. Neither the primary carrier or packaging material demonstrated high levels of absorption of sterilant or degradative changes during the chemiclave sterilization process.

- Holding Time Assessment
  The intent of the study was to verify that BIs not processed (transferred to growth medium and incubated) immediately following exposure are not negatively impacted. The BIs are not impacted if left at room temperature for 96 hours prior to transfer to growth medium.
- Recovery Protocols – Reduced Incubation Time (RIT)
  - Determination of Reduced Incubation for Chemiclave Sterilization Process (Modified TSB) with Delayed Incubation Post-Exposure
    The 72 hour RIT claim for chemiclave sterilization was determined to be still valid even when the Spore Strips are held for 96 hours post-exposure prior to transferring to growth medium.

In summary, the data provided demonstrates NAMSA Biological Indicator Spore Strip is substantially equivalent to the predicate device. The test results support a determination of substantial equivalence to the legally marketed predicate device, as well as demonstrate the NAMSA Biological Indicator Spore Strip is as safe, as effective, and performs as well as or better than the predicate device.