February 26, 2019

3M Company
Nadia Battah
Regulatory Affairs Associate
3m Center
Building 275-5w-06
St.paul, Minnesota 55144

Re: K183211
  Trade/Device Name: 3M Comply Hydrogen Peroxide Chemical Indicator 1248
  Regulation Number: 21 CFR 880.2800
  Regulation Name: Sterilization Process Indicator
  Regulatory Class: Class II
  Product Code: JOJ
  Dated: February 8, 2019
  Received: February 11, 2019

Dear Nadia Battah:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray Iii III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

Use the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 as an internal pack process indicator to verify exposure to vaporized hydrogen peroxide in the STERRAD® 100, STERRAD® 100S, STERRAD® NX (Standard and Advanced cycles), STERRAD® 100NX (Standard, Flex, Express and Duo cycles), STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles), STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express and Duo cycles), AMSCO® V PRO® 1 (Lumen cycle), AMSCO® V PRO® 1 Plus (Lumen and Non Lumen cycles), AMSCO® V PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles) and AMSCO® V-PRO® 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles) sterilizers. The chemical indicator bar turns from blue toward pink after exposure to vaporized hydrogen peroxide.

CONTINUE ON A SEPARATE PAGE IF NEEDED.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Office of Chief Information Officer
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PRASstaff@fda.hhs.gov

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510(k) Summary
for
3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248
K183211

Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact: Nadia Battah
Senior Regulatory Affairs Associate
Phone Number: (651) 733-0929
Fax Number: (651) 737-5320

Date of Summary: February 22, 2019
1. Device Name and Classification:
   
   Common or Usual Name: Chemical Indicator
   
   Proprietary Name: 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248
   
   Classification Name: Indicator, physical/chemical sterilization process
   
   Device Classification: Class II, 21 CFR § 880.2800
   
   Product Code: JOJ

2. Predicate Device:

   K170321 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248

3. Description of Device:

   The 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 consists of a non-cellulosic plastic material onto which a chemical indicator bar is printed. A comparison color match is also printed on the product to aid in color interpretation.

4. Indications for Use

   Use the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 as an internal pack process indicator to verify exposure to vaporized hydrogen peroxide in the STERRAD® 100, STERRAD® 100S, STERRAD® NX (Standard and Advanced cycles), STERRAD® 100NX (Standard, Flex, Express and Duo cycles), STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles), STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express and Duo cycles), AMSCO® V-PRO® 1 (Lumen cycle), AMSCO® V-PRO® 1 Plus (Lumen and Non Lumen cycles), AMSCO® V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles) and AMSCO® V-PRO® 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles) sterilizers. The chemical indicator bar turns from blue toward pink after exposure to vaporized hydrogen peroxide.
## 5. Summary of Technological Characteristics compared to Predicate Device

<table>
<thead>
<tr>
<th>Feature</th>
<th>Submission Device: K183211: 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248</th>
<th>Predicate Device (K170321): 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for use</td>
<td>Use the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 as an internal pack process indicator to verify exposure to vaporized hydrogen peroxide in the STERRAD® 100, STERRAD® 100S, STERRAD® NX (Standard and Advanced cycles), STERRAD® 100NX (Standard, Flex, Express and Duo cycles), STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles), STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express and Duo cycles), AMSCO® V-PRO™ 1 (Lumen cycle), AMSCO® V-PRO™ 1 Plus (Lumen and Non Lumen cycles), AMSCO® V-PRO™ maX (Lumen, Non Lumen, and Flexible cycles) and AMSCO® V-PRO™ 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles) sterilizers. The chemical indicator bar turns from blue toward pink after exposure to vaporized hydrogen peroxide.</td>
<td>Use the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 as an internal pack process indicator to verify exposure to vaporized hydrogen peroxide in the STERRAD® 100, 100S, NX® (Standard and Advanced cycles), 100NX® (Standard, Flex, Express and Duo cycles), AMSCO® V-PRO™ 1 (Lumen cycle), AMSCO® V-PRO™ 1 Plus (Lumen and Non Lumen cycles), and AMSCO® V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles) sterilizers. The chemical indicator bar turns from blue to pink after exposure to vaporized hydrogen peroxide.</td>
</tr>
</tbody>
</table>
| Sterilizers and Sterilization Cycles | STERRAD® 100  
STERRAD® 100S  
STERRAD® NX (Standard and Advanced cycles)  
STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles)  
STERRAD® 100NX (Standard, Flex, Express, and Duo cycles)  
STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express, and Duo cycles)  
AMSCO® V-PRO™ 1 (Lumen cycle)  
AMSCO® V-PRO™ 1 Plus (Lumen and Non Lumen cycles)  
AMSCO® V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles)  
AMSCO® V-PRO™ 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles) | STERRAD® 100  
STERRAD® 100S  
STERRAD® NX (Standard and Advanced cycles)  
STERRAD® 100NX (Standard, Flex, Express, and Duo cycles)  
AMSCO® V-PRO™ 1 (Lumen cycle)  
AMSCO® V-PRO™ 1 Plus (Lumen and Non Lumen cycles)  
AMSCO® V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles) |
| Substrate | Polyethylene | Identical |
| Biocompatibility | The exposure to health care professional is minimal and well below any identified toxic thresholds for the compounds. | Identical |
| Color Change | Blue toward pink | Identical |
| Detection | Hydrogen Peroxide | Identical |
| Stability of the endpoint reaction | At least one month (4 weeks) | Identical |
| Shelf life | Two (2) years | Identical |
6. Summary of Non-Clinical Testing

The 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 is identical to the previously cleared device of the same model number (the predicate) which is sold under the tradename 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 (K170321). As no change has been made to the device materials, performance specifications, or fundamental technology, the biocompatibility and nonclinical testing provided in K170321 was referenced in this submission to support performance of the device in the claimed sterilizers.

To demonstrate performance in the newly claimed sterilizers and cycles, nonclinical testing was performed in accordance with the FDA Guidance for Industry and Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators, issued December 19, 2003. Reference Table 6.1 for testing completed in the AMSCO® V-PRO™ 60 Low Temperature Sterilization System (Lumen, Non-Lumen and Flexible cycles), STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles), and STERRAD® 100NX with ALLClear™ Technology (Standard, Flex and Express cycles) sterilizer.

Table 6.1 Summary of Nonclinical Testing

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color Change in Health Care Facility Cycle</td>
<td>Pass</td>
</tr>
<tr>
<td>Minimum Exposure Parameters to Affect the Change of the Indicator in Health Care Facility Cycle</td>
<td>Pass</td>
</tr>
<tr>
<td>End Point Color Stability</td>
<td>Pass</td>
</tr>
</tbody>
</table>

7. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 is as safe, as effective, and performs as well as or better than the legally marketed device, the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 cleared under K170321, Class II (21 CFR 880.2800), product code JOJ.