510(k) Summary of Safety and Effectiveness

510k No.:

Submitter:

- SPSmedical Supply Corp.
  6789 West Henrietta Road
  Rush, NY 14543 U.S.A.
  Phone: (585)-359-0130  Fax: (585)-359-0167

- Establishment FDA Registration No.: 1319130

- Date Summary was Prepared  January 14th, 2011

- Gary J. Socola
  Printed name of person submitting for 510(k)

  [Signature]
  Signature of person submitting for 510(k)

- Vice President, Scientific Affairs
  Title of person submitting for 510(k)

Device Name and Classification

Trade Name: SPSmedical Vaporized Hydrogen Peroxide Chemical Indicators

Classification Name: Sterilization Process Chemical Indicator

Common Name: Vaporized Hydrogen Peroxide Chemical Indicators

Device Classification: General Hospital - Class II, Regulation Number 880.2800

Product Code: 80JOJ

Predicate Device: SPSmedical Vaporized Hydrogen Peroxide Chemical Indicators (K030680 and K090650)
Device Description:

SPSmedical Vaporized Hydrogen Peroxide (H₂O₂) Chemical Indicators are process indicators which are cleared for use in verifying exposure to vapor hydrogen peroxide in the STERRAD® 100S, 200, 100NX, NX, STERIS® V-Pro lumen and non lumen sterilization processes. Testing has been performed which validates the SPSmedical Vaporized Hydrogen Peroxide (H₂O₂) Chemical Indicators for use in the STERIS® V-Pro flexible sterilization cycle and the STERIS® V-Pro maX sterilizer.

Indicators will identify if an item has seen H₂O₂ during the STERIS® V-Pro flexible sterilization process by changing to a Blue signal color. They provide a visual indication to help distinguish between processed and unprocessed items.

Intended Use:

The SPSmedical Vaporized Hydrogen Peroxide (H₂O₂) Chemical Indicators are process indicators used to verify exposure to the STERIS® V-Pro maX flexible sterilization process. They are intended to be used by health care providers with articles such as sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed items.

Statement of Similarity to the Legally Marketed Predicate Device:

- Have the same intended use
- Have the same device design
- Incorporate the same technical characteristics
- Incorporate the same materials
- Have the same endpoint color change
- Have the same shelf life
- Have the same storage conditions
- Packaged using the same materials and processes

Non-Clinical Testing:

Verification and validation tests were performed as a result of a Failure Mode and Effects Analysis (FMEA) assessment.

Various testing, including testing to AAMI/ANSI/ISO 11140:2005 requirements for indicators being run in vaporized hydrogen peroxide sterilization processes was performed. Testing also included simulated use in the STERIS® V-Pro maX vaporized hydrogen peroxide flexible sterilization cycle. Multiple lots of indicators with various levels of shelf life were included in testing.

All lots of SPSmedical Vaporized Hydrogen Peroxide Chemical Indicators gave acceptable results for all test performed.

Conclusion:

For all the foregoing reasons, SPSmedical believes that the SPSmedical Vaporized Hydrogen Peroxide Chemical Indicators are safe and effective when used for routine monitoring of STERIS® V-Pro maX sterilizer running a vaporized hydrogen peroxide flexible sterilization cycle and can be safely marketed in the United States.
Mr. Gary J. Socola  
Vice President, Scientific Affairs  
SPSmedical Supply, Corporation  
6789 West Henrietta Road  
Rush, New York 14543  

APR 15 2011

Re: K110152  
Trade/Device Name: SPSmedical H₂O₂ Chemical Indicator  
Regulation Number: 21 CFR 880.2800  
Regulation Name: Sterilization Process Indicator  
Regulatory Class: II  
Product Code: JOJ  
Dated: January 14, 2011  
Received: January 19, 2011

Dear Mr. Socola:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucmm115809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. 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 yours,

[Signature]

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
INDICATIONS for USE STATEMENT

Applicant: SPSmedical Supply Corp.

510(k) Number (if known): ______________

Device Name: SPSmedical H₂O₂ Chemical Indicator

Indications For Use:

The SPSmedical H₂O₂ Chemical Indicators are indicated for use as process indicators for all vaporized hydrogen peroxide cycles in the STERRAD® 100S, 200, 100NX, NX and STERIS® V-Pro1, V-Pro 1 Plus and V-Pro maX sterilizers. They are intended to be used by health care providers with articles such as sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed items. Indicators change to a signal color of Blue after exposure to vapor hydrogen peroxide.

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>GPS-250R</td>
<td>Indicator Strip</td>
</tr>
<tr>
<td>GPS-250Y</td>
<td>Indicator Strip</td>
</tr>
<tr>
<td>GPL-2000R</td>
<td>Indicator Label</td>
</tr>
<tr>
<td>GPL-2000Y</td>
<td>Indicator Label</td>
</tr>
<tr>
<td>HT-048</td>
<td>Indicator Tape</td>
</tr>
<tr>
<td>HT-036</td>
<td>Indicator Tape</td>
</tr>
<tr>
<td>5093</td>
<td>Indicator Card</td>
</tr>
</tbody>
</table>

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

(Please do not write below this line-continue on another page of needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page of ___