DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 13, 2016

J.R. Parker, LLC
Mr. J. Richard Parker
President
1665 Warpath Road
West Chester, Pennsylvania 19382-1745

Re: K152538
Trade/Device Name: JRP Wound Spreader
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: Class I
Product Code: GAD
Dated: December 23, 2015
Received: February 25 2016

Dear Mr. Parker:

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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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)*
K152538

Device Name
JRP Wound Spreader

Indications for Use *(Describe)*
The JRP Wound Spreader is a non-invasive superficial wound retractor with integrated guard that is used for wound care and positioning of small superficial wounds in the skin of up to 1/4" in width, 1/4" in depth and 1/2" in length.

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.**

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

***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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary K152538



510(k) Summary
as required by 807.92(c)

## JRP Wound Spreader

Submission Date: August 23 2015


Submitted by: J.R. Parker, LLC
1665 Warpath Road
West Chester, PA 19382
USA
Registration No.: 20-4971893
Tel: +1-484-410-3592
Email: intercept@centurylink.net

Application Contact: J. Richard Parker, President

J.R. Parker, LLC
1665 Warpath Road
West Chester, PA 19382
USA
Tel: +1-484-410-3592
Email: intercept@centurylink.net

Correspondent Contact: J. Richard Parker, President


Device Trade Name: JRP Wound Spreader

Common Name: Topical Wound Retractor
Classification Name: Manual, General Use Surgical Device
Regulation No.: 878.4800
Classification Code: GAD
Regulatory Class: Class 1

Predicate Device: Endo Retract II K914190
Classification Name: Manual, General Use Surgical Device
Regulation No.: 878.4800
Classification Code: GAD
Regulatory Class: Class 1

Description of Device: The JRP Wound Spreader is a manually operated handheld non-invasive superficial wound retractor with an integrated guard that can accommodate a needleless syringe for the purpose of facilitating the retraction, observing the wound and flushing of small superficial wounds in the skin if deemed necessary. The JRP Wound Spreader consists of an array of four small tensioning fingers, which can be positioned on the skin astride a small superficial wound or incision.

# 510(k) Summary K152538

**Physical Characteristics:**
For wound positioning only, the tensioning fingers at the distal end of the device are placed against the skin, astride the wound. Using one hand to grasp the barrel of the JRP Wound Spreader, the device is pushed distally towards the wound, causing the retractor fingers to move away from the wound. The friction of the fingers against the skin effects the positioning of the wound so as to improve visualization. If flushing is desired, the above method is modified for use with a syringe by using one hand to grasp the barrel and apply downward pressure until the distal surface contacts the skin, providing an envelope for flushing of the positioned wound via the attached syringe through the discharge port of the spreader assembly. The plunger of the syringe may then be depressed using the second hand. In this operation, the Wound Spreader barrel functions secondarily as a sway stabilizer and is clear and colorless, allowing the operator to observe the procedure.

**Performance Characteristics:**
As the JRP Wound Spreader is applied against the skin as described above, the fingers meet the skin first. The coils enhance the spring action of these fingers, allowing them to move gently outward, pulling the skin slightly taut. This spring action applies tension across the wound and maintains wound position without entering into the wound. However, the operator must maintain the downward pressure in order to maintain wound positioning.

**Intended Use:**
The JRP Wound Spreader is a non-invasive superficial wound retractor with an integrated guard that is used for wound care and positioning of small superficial wounds in the skin of up to 1/4" in width, 1/4'' in depth and 1/2" in length.

**Material and Manufacturing Process:**
The device consists of three standard-sized acrylic tubes and an acrylic disk fabricated from standard medical grade material. The device also makes use of tensioning fingers made from medical grade Type 316 stainless steel. For the final marketed product, the tensioning fingers will be passivated prior to assembly. The tubular parts and retractor arms are cut to size and glued with medical grade adhesive at contact surfaces. All manufacturing and assembling will be conducted in accordance with cGMP requirements. This unit will be manufactured sterile.

# 510(k) Summary K152538

**Comparisons Summary and Technical Characteristics of the JRP Wound Spreader Compared to the Predicate Device the Endo Retract II:**

Both the JRP Wound Spreader and the Endo Retract II make use of an array of tensioning fingers which are positioned on and against the skin to form, shape, open and position a wound or incision. Both devices also maintain the wound or incision position open for a desired procedure by use of pressure against the skin. The JRP Wound Spreader has the same intended use to position wounds or incisions as the predicate device and utilizes materials that are already in use in other medical devices. No new issues of safety are introduced by using this device. The JRP Wound Spreader design and effectiveness are addressed here and through performance and safety testing as sited in the submission. This device is found to have no new safety issues because the arms used for deformation at the wound site do not enter the wound. The JRP Wound Spreader is topical and non-invasive compared to the predicate device. While the principle mechanism of action is the same for both devices, i.e., the application of tension across the wound, the JRP Wound Spreader employs a surface friction method to apply this tension, in contrast to the predicate device, which employs outward pressure directly against the edges of the wound. While the predicate retractor is indicated for lengthy surgical procedures involving wounds and incisions, the invasive nature of its action makes it unsuitable for use in small superficial topical wounds to the skin. Conversely, JRP Wound Spreader's design limits its use solely to the care of superficial wounds to the skin. Additionally, the JRP Wound Spreader's design facilitates the flushing of the indicated wound.

**Performance Testing:**

Several tests were performed and confirmed that the luer slip fit connection to the syringe is secure and does not leak under pressure. Also a twisting and flexion test to the luer connection confirmed a substantial bond. The 40-person study comprised of 160 performance and assembly tasks as sited in our submission was 97% successful and indicated that the JRP Wound Spreader is effective in positioning wounds compared to the predicate device and presented no new safety issues supporting a determination of substantial equivalence.

**Summary Conclusion:**

The JRP Wound Spreader and the Endo Retract II both position and maintain the positioning of wounds and incisions by use of an array of small retractor fingers which make use of an outward projection applied against the skin. The effective history of the Endo Retract II is evident. The JRP Wound Spreader was designed to open small wounds and incisions, position and maintain positioning in a totally non-invasive topical manner using the same basic method as the Endo Retract II does invasively. Both the performance and the safety of the JRP Wound Spreader are qualified and

# 510(k) Summary K152538

quantified by the 40-person study involving 160 tasks (performance, safety and assembly) with a 97% success rate. Several tests were also conducted to the luer slip fit syringe connection, applying higher than normal pressure to the connection with a 100% success outcome. The testing, engineering and design logic dictate that the JRP Wound Spreader is substantially equivalent to the Endo Retract II in performance with no new safety issues.