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

March 9, 2016

Spinal Resources, Incorporated
% Mr. Kenneth Maxwell
Regulatory and Quality Specialist
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K152662
Trade/Device Name: S-Wire
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY, JDW
Dated: January 29, 2016
Received: February 1, 2016

Dear Mr. Maxwell:

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic 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 on last page.

510(k) Number *(if known)*
K152662

Device Name
S-Wire

Indications for Use *(Describe)*

The S-Wire is intended to perform as temporary fixation and stabilization unit of bone fractures and as guidance at insertion of implants into the skeletal system.

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)*

510(K) SUMMARY

Submitter's Name:	Spinal Resources, Inc.
Submitter's Address:	274 E Eau Gallie Blvd Unit 303 Indian Harbour Beach Fl 32937
Submitter's Telephone:	904-540-9049
Contact Person:	Kenneth C. Maxwell II Empirical Testing Corp. 719. 291.6874
Date Summary was Prepared:	07 March 2016
Trade or Proprietary Name:	S-Wire
Common or Usual Name:	Pin, Fixation, Smooth Pin, Fixation, Threaded
Classification:	Class II per 21 CFR §888.3040
Product Code:	HTY and JDW
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The S-Wire is composed of wires manufactured from stainless steel per ASTM F138 and nitinol per ASTM F2063. The wires are available in lengths of 150-550mm and diameters of .7-1.6mm. The S-wire is available with the following tip styles: Diamond Smooth, Diamond Threaded, Round Smooth, Round Threaded, Trocar Smooth, Trocar Threaded, and Diamond Suture Passer.

INDICATIONS FOR USE

The S-Wire is intended to perform as temporary fixation and stabilization unit of bone fractures and as guidance at insertion of implants into the skeletal system.

The indications for use for the S-wire is similar to that of the predicate device.

Table 5-1 Predicate Device

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K060654	DSI Pins and Wires	Delta Surgical Instruments	Primary

CONCLUSION

The overall technology characteristics and the geometrical analysis comparing the devices leads to the conclusion that the S-wire is substantially equivalent to the predicate device.