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

December 22, 2014

Agent Medical, LLC
% Mr. Al Lippincott
Engineering Consulting Services, Incorporated
3150 E. 200th Street
Prior Lake, Minnesota 55372

Re: K142528
Trade/Device Name: Agent Medical - ArthroBridge System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 16, 2014
Received: October 28, 2014

Dear Mr. Lippincott:

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,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) NUMBER: **K142528**

DEVICE NAME: **Agent Medical - ArthroBridge System**

The *Agent Medical ArthroBridge System* is intended to facilitate bone healing following reduction and fracture fixation of the small bones.

The *Agent Medical - ArthroBridge System* **is indicated for use** for small bone fractures and osteotomy fixation and for distal phalangeal inter-digital fusion of the fingers and toes.

The Agent Medical - ArthroBridge System is not for spinal use.

Prescription Use **XXXX** AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Agent Medical - ArthroBridge System - K142528 - 510(k) Summary:

510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

NAME OF FIRM: Agent Medical, LLC
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Suite 102
Richmond, VA 23238
USA

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372
Tel. No. 952-492-5858
e-mail: allippincott@msn.com

DATE: December 9, 2014

TRADE NAME: **Agent Medical – ArthroBridge System**

COMMON NAME: Intramedullary Bone and Compression Screw System

DEVICE NAME: Screw, Fixation, Bone

CLASSIFICATION: Smooth or Threaded Metallic Bone Fixation Fastener,
Class II (21 CFR, Sec. 888.3040)

DEVICE PRODUCT CODE: **HWC**

SUBSTANTIALLY EQUIVALENT DEVICE
Integra/Kinetikos – KMI Kompressor™ Compression Screw (**K024233 & K040356**)
BioPro – Kwick-Wire™ Universal Screw System (**K130298**)
Nextremity - Nextra™ Hammertoe Correction System (**K122031)**
Pioneer/Tornier – StayFuse™ Intramedullary Fusion Device (**K990804**)
BioPro – Go-Ez™ Screw System (**K081149**)

Agent Medical - ArthroBridge System - K142528 - 510(k) Summary:

DEVICE DESCRIPTION:

The Agent Medical - ArthroBridge System is an intramedullary small joint arthrodesis/fusion system for fixation of osteotomies, fractures and reconstruction of the phalanges of the lesser digits in the foot and hand. The Agent Medical - ArthroBridge System is a 2-piece cannulated compression screw system composed of 1). A threaded Proximal Module (in a 4.0, 4.5 & 5.0mm size) that is placed within the proximal phalangeal medullary canal, and 2). A Screw with low profile head (in lengths of 25, 30, 35, 40, 45 and 50mm) that is introduced/threaded into the previously inserted Proximal Module. The Proximal Module is cannulated to fit over an insertion instrument and the Screw is cannulated to fit over a .035" K-wire for guided insertion of both components within the phalangeal digit medullary canal. The threaded advancement of the Screw body within the stationary threaded Proximal Module allows internal compression across the debrided digit joint space for stabilization and eventual fusion/ arthrodesis – and for bone fixation and joint deformity correction. The threaded Proximal Module and Screw with low profile head are manufactured from high strength Ti6Al4V ELI Titanium Alloy with an Anodized Type II surface. Disposable, single use, Cannulated Drills, Guide Wires, and Driver/Depth Gauge instruments are available for insertion of the system. Removal (when necessary) of the device is carried out percutaneously. All Implants and Instruments are packaged '**Sterile**' for single use. The method of sterilization is Ethylene Oxide.

INTENDED USE:

The *Agent Medical - ArthroBridge System* is intended to facilitate bone healing following reduction and fracture fixation of the small bones.
The *Agent Medical - ArthroBridge System* **is indicated for use** for small bone fractures and osteotomy fixation and for distal phalangeal inter-digital fusion of the fingers and toes.
The Agent Medical ArthroBridge System is not for spinal use.

EQUIVALENCE:

The *Agent Medical - ArthroBridge System* is Substantially Equivalent(SE) to the predicate systems (as listed). No nonclinical testing was used in the determination of substantial equivalence.

SUMMARY OF TECH-NOLOGICAL CHARACTERISTICS

The *Agent Medical - ArthroBridge System* is Similar in Material, Design, and Indications to the listed predicate devices.

CONCLUSION:

The *Agent Medical - ArthroBridge System* has similar indications for use, materials, dimensions, and designs when compared to the predicate devices. An engineering/dimensional comparison to the predicate devices was performed to demonstrate Substantial Equivalence (SE). Based on these similarities, the *Agent Medical – ArthroBridge System* is substantially equivalent to the predicates identified in the 510(k) Summary.