



Food and Drug Administration  
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Renovis Surgical Technologies, Incorporated  
% Sharyn Orton, Ph.D.  
Senior Consultant  
MEDIcept Incorporated  
200 Homer Avenue  
Ashland, Massachusetts 01721

September 25, 2015

Re: K152193

Trade/Device Name: Renovis Anterior Cervical Plate System  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: Class II  
Product Code: KWQ  
Dated: July 30, 2015  
Received: August 5, 2015

Dear Dr. Orton:

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

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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,

**Mark N. Melkerson -S**

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 (if known)

K152193

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Device Name

Renovis Anterior Cervical Plate System

### Indications for Use (Describe)

The Renovis Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2-C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of fusion in patients with the following conditions:

- degenerative disc disease(DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- trauma (i.e., fracture or dislocation)
- spinal stenosis
- tumor
- pseudoarthrosis
- failed previous fusion

**WARNING:** The Renovis Anterior Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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.

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**Traditional 510(k) Summary  
as required by 21 CFR 807.92(a)**

A) Submitted by: Renovis Surgical Technologies  
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Vice President of Quality Assurance

Consultant: Sharyn Orton, Ph.D.  
MEDIcept, Inc.  
200 Homer Ave  
Ashland, MA 01721

Prepared: September 23, 2015

B) Classification Name: Spinal Intervertebral Body Fixation Orthosis

Common Name: Anterior Cervical Plate, Anterior Cervical Spinal Fixation System

Proprietary Name: Renovis Anterior Cervical Plate System

Device Class: Class II

Regulation and Product Code: 21 CFR 888.3060  
KWQ

Classification panel: Orthopedic

C) Predicate: K030866 Synthes Anterior CSLP System

D) Device Description

The Renovis Anterior Cervical Plate System consists of various shapes and sizes of plates and screws, and associated instruments. The plates are available in multiple lengths to accommodate single or multi-level surgeries. The plates and screws are manufactured from titanium alloy and the locking clip is manufactured from nickel-titanium alloy.

#### E) Intended Use/Indications For Use:

The Renovis Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2-C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of fusion in patients with the following conditions:

- degenerative disc disease(DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- trauma (i.e., fracture or dislocation)
- spinal stenosis
- tumor
- pseudoarthrosis
- failed previous fusion

**WARNING:** The Renovis Anterior Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

#### F) Substantial Equivalence Comparison

The Renovis Anterior Cervical Plate System and predicate devices (K030866 Synthes Anterior CSLP System; K945700 Synthes Anterior Cervical Vertebrae Plate System; K102820 Trestle Luxe Anterior Cervical Plating System, Alphatec Spine) have the same intended use/ Indications for Use, are manufactured from the same or similar materials, have a screw retention system; and have similar dimensions.

#### H) Performance Testing

Performance testing of the Renovis Anterior Cervical Plate System under ASTM F1717, including static axial compression bending, static torsion and dynamic axial compression bending, was conducted and found to be acceptable. Corrosion testing under ASTM F2129 was conducted and found to be acceptable. Auger Emission Spectroscopy (AES) analysis of the nitinol clip was conducted and found to be acceptable. Screw push-out testing was conducted per protocol and found to be acceptable.

#### I) Compliance with Standards and Guidance

- ASTM F136-13 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F2063-12 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants
- ASTM A564-13 Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes
- ASTM B211-12e1 Standard Specification for Aluminum and Aluminum-Alloy Rolled or Cold Finished Bar, Rod, and Wire
- ASTM B221-13 Standard Specification for Aluminum and Aluminum-Alloy Extruded Bars, Rods, Wire, Profiles, and Tubes

- EN 10088-3:2005 Stainless steels – Part 3: Technical delivery conditions for semi-finished products, bars, rods, wire, sections and bright products of corrosion resisting steels for general purposes
- ASTM F2129-08 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices
- ASTM F1717-14 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
- ASTM F983-86 (Reapproved 2013) Standard Practice for Permanent Marking of Orthopaedic Implant Components
- ASTM F565-04 (Reapproved 2013) Standard Practice for Care and Handling of Orthopedic Implants and Instruments
- ISO 17665-1:2006 Sterilization of health care products – Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices
- ASTM F86-13 Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants

Guidance for Industry and FDA Staff - Spinal System 510(k)s, May 3, 2004, where applicable to anterior cervical plate systems.

### *Conclusion*

Given testing and other technological comparisons, the Renovis Anterior Cervical Plate System is substantially equivalent to the predicate devices.