DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 27, 2016

Cryptych Pty Ltd.
% Mr. Dave Thomson
Director and QA /RA Manager
Strategic Medical Compliance
42 Fountains Road
Narara, NSW 2250 Australia

Re: K160385
Trade/Device Name: Precision Screw
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 17, 2016
Received: June 27, 2016

Dear Mr. Thomson:

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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K160385

Device Name
Precision Screw

Indications for Use *(Describe)*

The Precision Screw is intended for establishing fixed reference point(s) in patients undergoing Stereotactic Surgery for procedures in the cortical bone of the vertebrae. The Precision Screw can be used as an accessory with frameless navigation systems.

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.

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510(K) SUMMARY AS PER 21 CFR 807.92 (C)

M.1 SUBMITTER

Submitter: Cryptych Pty Ltd.

Address: Suite 106, 275 Alfred Street, North Sydney, NSW 2060 AUSTRALIA

Phone: +61 414 899 799

Contact Person: David Thomson

Date Prepared: 4th December 2015, updated 22nd July 2016

M.2 DEVICE

Name of Device: Precision Screw

Model: CRY01

Common or Usual Name: Fiducial Bone Screw or Stereotactic Instrument

Classification Name: Stereotactic Instrument or Accessory (21 CFR 882.4560)

Regulatory Class: II

Product Code: OLO

Reason for Submission New Device

M.3 PREDICATE DEVICE

Lorenz Fiducial Screw, K010427

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

M.4 DEVICE DESCRIPTION

The **Precision Screw** is a self-drilling metallic fixation device used only as a reference point during stereotactic procedures. Commonly known as a Fiducial Screw or a stereotaxic instrument, the Precision Screw can be used as an accessory with frameless navigation systems, as appropriate, from other manufacturers.

M.5 INDICATIONS FOR USE

The Precision screw is intended for establishing fixed reference point(s) in patients undergoing Stereotactic Surgery for procedures in the cortical bone of the vertebrae. The Precision Screw can be used as an accessory with frameless navigation systems.

M.6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Feature	Precision Screw K160385	Lorenz Fiducial Screw K010427
Intended use	Fiducial marker used by a frameless navigation system to identify a fixed reference point during surgery	Fiducial marker used by a frameless navigation system to identify a fixed reference point during surgery
Anatomical Site	Vertebral bone	Bone
Material	Biocompatible metal (Titanium alloy)	Biocompatible metal (Titanium)
Reprocessing	Provided sterile, Single use	User sterilized, Single use
Insertion method	Self tapping threads inserted with a mechanical driver	Self tapping threads inserted with a mechanical driver

The Precision screw has similar characteristics to the Lorenz predicate. Notable differences are that the Precision screw is delivered sterile and is specified for vertebral use. However, these differences have been shown to not impact the safety and effectiveness of the Precision screw:

- Sterilization has been validated
- Viable anatomic locations on the vertebrae were evaluated for safety and identified in the labeling.

Since most features are equivalent and new features do not add risk, the Precision screw system is equivalent to the predicate.

1.7 PERFORMANCE DATA

Since the predicate device was cleared based in part on the results of clinical studies, and since the comparison of bench testing to clinical outcomes is well understood for this type of device, clinical testing was not required to support substantial equivalence. The non-clinical data provided supports the safety of the device and its technological equivalence to the predicate device.

The following performance data were provided in support of the substantial equivalence determination.

- Biocompatibility testing

The biocompatibility evaluation for the Precision Screw was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The Precision Screw is considered are considered as permanent implants. The titanium material conforms to ASTM F136 for chemical composition and is suitable for surgical implant applications.

- Mechanical strength and integrity testing

The mechanical testing performed on the Precision Screw demonstrates that it meets the performance standards identified in ASTM F543-13 and ISO 6475:1989, for determining the torsional properties and driving torque of the Precision Screw.

- Visual Acuity using a suitable frameless navigation system

The visibility of the Precision Screw on O-Arm images and the suitability for its use for spinal navigation was assessed by inserting Precision Screws into a Spinal Bone Model developed specifically for this testing. The tests performed on these screws serve to confirm that the screws are highly visible and fit for the purpose they are intended for in the operative setting.

1.8 SUMMARY

The Precision Screw is substantially equivalent to the Lorenz Fiducial Screw both in terms of its intended use, design and the fundamental scientific technology. The Precision Screw was found to have a safety and effectiveness profile that is similar to the predicate device. The Lorenz Fiducial Screw was cleared by FDA in K010427.

1.9 CONCLUSIONS

The Precision Screw is substantially equivalent to the predicate device (Lorenz Fiducial Screw K010427).