DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Nvision Biomedical Technologies, LLC
% Allison Komiyama, Ph.D., RAC
Principal Consultant
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2834 Hawthorn Street
San Diego, California 92104

September 2, 2016

Re: K161524
Trade/Device Name: Tangis Anterior Cervical Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 2, 2016
Received: August 3, 2016

Dear Dr. Komiyama:

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,

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 below.

510(k) Number *(if known)*
K161524

Device Name
Tangis Anterior Cervical Plate

Indications for Use *(Describe)*
The Tangis Anterior Cervical Plate is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:
• degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
• spondylolisthesis,
• trauma (i.e. fractures or dislocations),
• tumors,
• deformity (defined as kyphosis, lordosis, or scoliosis),
• pseudarthrosis,
• failed previous fusion,
• spinal stenosis

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

DATE PREPARED
May 31, 2016

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PROPRIETARY NAME OF SUBJECT DEVICE
Tangis Anterior Cervical Plate

COMMON NAME
Anterior Cervical Plate

DEVICE CLASSIFICATION
Spinal intervertebral body fixation orthosis
(21 CFR 888.3060, Product Code KWQ, Class II)

PREMARKET REVIEW
ODE/DOD/ASDB
Orthopedic Panel

INDICATIONS FOR USE
The Tangis Anterior Cervical Plate is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- spondylolisthesis,
- trauma (i.e. fractures or dislocations),
- tumors,
- deformity (defined as kyphosis, lordosis, or scoliosis),

- pseudarthrosis,
- failed previous fusion,
- spinal stenosis

DEVICE DESCRIPTION

The Tangis Anterior Cervical Plate is intended for anterior screw fixation of the plate to the cervical spine. The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-drilling and self-tapping bone screws using an anterior approach. Plates are available in a variety of lengths (20 mm – 92 mm), addressing multiple levels of fixation (one to four). The plate incorporates graft visualization holes on the longitudinal center line for intraoperative visualization. Bone screws are available in three diameters (3.75 mm, 4.25 mm, and 4.75 mm) and a variety of lengths (10 mm – 20 mm). All components are made from titanium alloy per ASTM F136.

PREDICATE DEVICE IDENTIFICATION

The Tangis Anterior Cervical Plate is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K151553	Anterior Cervical Plate System / Osteomed Implantes, LTDA	✓
K031276	ACLP System / Synthes Spine	
K022965	Blackstone™ “Classic” Anterior Cervical Plate / Blackstone Medical, Inc.	

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Tangis Anterior Cervical Plate. The following tests were performed to demonstrate safety based on current industry standards:

- Static and dynamic compression (per ASTM F1717)
- Static torsion (per ASTM F1717)

The results of these tests indication that the Tangis Anterior Cervical Plate is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES

Nvision believes that the Tangis Anterior Cervical Plate is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design and dimensions, and uses similar or identical materials as the devices cleared in K151553, K031276, and K022965. The subject device has the same intended use and similar technological characteristics to the devices cleared in K151553 and K022965. The device has similar instrumentation to the device cleared in K151553, and K031276.

CONCLUSION

The Tangis Anterior Cervical Plate is considered substantially equivalent to the predicate devices based on the testing performed, the identical indications for use, and similar technological characteristics. Based on the testing performed, including static and dynamic compression as well as static torsion (per ASTM F1717), it can be concluded that the subject device does not raise new issues of safety or efficacy compared to the predicate devices.