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

March 18, 2015

Syntec Scientific Corporation
c/o Mr. Kavin Chu
Syntec Scientific Corporation – Taipei Office
3F., No.96, Sec. 3, Zhongxio East Road Da'An Dist.
Taipei, TAIWAN 10652

Re: K142001
Trade/Device Name: Syntec Wetali Orthodontic Mini Screws
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: February 3, 2015
Received: February 12, 2015

Dear Mr. Chu:

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,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental 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)*
K142001

Device Name
SYNTEC WETALI ORTHODONTIC MINI SCREWS

Indications for Use *(Describe)*
THE SCREWS ARE INDICATED FOR USE AS A FIXED ANCHORAGE FOR ATTACHMENT OF ORTHODONTIC APPLIANCES TO FACILITATE THE ORTHODONTIC MOVEMENT OF TEETH. THEY ARE USED TEMPORARILY AND ARE REMOVED AFTER ORTHODONTIC TREATMENT HAS BEEN COMPLETED. THEY ARE INTENDED FOR SINGLE USE ONLY.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SYNTEC SCIENTIFIC CORPORATION
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E-mail: fda@eagleseye.com.tw Regulatory Affairs Manager

This summary of 510(k) information is being submitted in accordance with the requirement of SMDA 1990 and 21CFR 807.92.

510(k) SUMMARY

Submitted By:	Syntec Scientific Corporation
Address:	No.2, Kung San Road Chuan Shing Industrial Zone, Shen Kang, Chang Hua Hsien, Taiwan R.O.C. TEL: +886-4-798-7099 FAX: +886-4-798-7077
Date Summary Prepared:	June 25, 2014
Contact person:	Kavin Chu
Name of the device:	Syntec Wetali Orthodontic Mini Screws
Trade or proprietary name:	Syntec Wetali Orthodontic Mini Screws
Common or usual name:	Ortho Anchor Screws
Classification name:	Endosseous Dental Implants
Produce code:	OAT
Regulation number:	872.3640
Class:	Class II
Predicate devices:	Syntec Orthodontic Mini Screws (K090476)

1. Description of the Device

The screws are manufactured from commercially SUS316L (stainless steel) and Ti6AL-4V (Titanium alloy). The screws are available with thread diameter are from 1.4mm to 2.0 mm, and total thread lengths from 6.0mm to 12.0mm. The minor technological modification for Syntec Wetali Orthodontic Mini Screws is re-designed self-drilling angle for more easily insertion and removal. The design of smooth curve surface of screw head is comfortable to patient and the screws with or without a 0.7mm diameter hole can supply different orthodontic methods for orthodontists.

2. Intended Use

The screws are indicated for use as a fixed anchorage for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. They are used temporarily and are removed after orthodontic treatment has been completed. They are intended for single use only.

3. Technological Characteristics, comparison to predicate device

Technically, the Syntec Wetali Orthodontic Mini Screws is identical to the Syntec Orthodontic Mini Screws cleared for market in 510(k) K090476 and essentially equivalent to the other predicate. The indications for use for the Syntec Wetali Orthodontic Mini Screws are patterned after the predicate devices and supported by an extensive collection of literature references.

	Subject device	Predicate Device
Device Name	Syntec Wetali Orthodontic Mini Screws	Syntec Orthodontic Mini Screws
Applicant	Syntec Scientific Corporation	Syntec Scientific Corporation
510(k)	K142001	K090476
Material	Surgical Stainless Steel (SUS316L) and Surgical Titanium Alloy (Ti6AL-4V)	Surgical Stainless Steel (SUS316L) and Surgical Titanium Alloy (Ti6AL-4V)
Thread Diameter	From 1.4mm to 2.0mm	From 1.3mm to 2.0mm
Thread Length	From 6.0mm to 12.0mm	From 5.0mm to 12.0mm
Screw Head Design	The screws are with or without a 0.7mm diameter hold.	The screws are with or without a 0.65mm diameter hold.

4. Performance Data (Nonclinical Testing)

The procedure of evaluating the pull out strength and insertion torque was according to the standard of ASTM-F543. Both of comparative testing was done to our own predicate device to demonstrate substantial equivalence.

5. Substantial Equivalence

The Syntec Wetali Orthodontic Mini Screws is as safe and effective as Syntec Orthodontic Mini Screws (K090476). The Syntec Wetali Orthodontic Mini Screws has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Syntec Wetali Orthodontic Mini Screws and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Syntec Wetali Orthodontic Mini Screws is as safe and effective as Syntec Orthodontic Mini Screws (K090476). Thus, the Syntec Wetali Orthodontic Mini Screws is substantially equivalent and presents no new concerns about safety and effectiveness.