September 17, 2021

Syntec Scientific Corporation
% Nicole Tseng
Senior Regulatory Affairs Specialist
Syntec Scientific Corporation - Taipei Office
3F., No.96, Sec. 3, Zhongxio East Road Da'An Dist.,
Taipei, R.O.C. 10652
TAIWAN

Re: K202790
Trade/Device Name: Syntec Orthodontic Mini Screw Extended System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: OAT
Dated: August 8, 2021
Received: August 18, 2021

Dear Nicole Tseng:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202790

Device Name
Syntec Orthodontic Mini Screw Extended System

Indications for Use *(Describe)*
The screws are intended to provide fixed anchorage for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. They are used temporarily and are intended to be removed after orthodontic treatment has been completed. The screws 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

510(k) K202790 Summary

Submitted By:	Syntec Scientific Corporation
Address:	Syntec Scientific Corporation - Taipei Office 3F., No.96, Sec. 3, Zhongxio East Road Da'An Dist., Taipei, Taiwan 10652 R.O.C. TEL: +886-4-798-7099 FAX: +886-4-798-7077
Date of Summary Prepared:	2021-09-17
Contact Person:	Nicole Tseng
Name of the Device:	Syntec Orthodontic Mini Screw Extended System
Trade or Proprietary Name:	Syntec Orthodontic Mini Screw Extended System
Common or Usual Name:	Ortho Anchor Screws
Classification Name:	Endosseous Dental Implant
Product Code:	OAT
Regulation Number:	21 CFR 872.3640
Class:	Class II
Predicate Device:	Syntec Orthodontic Mini Screw (K090476)
Reference Device:	Syntec Wetali Orthodontic Mini Screws (K142001)
Prior Submission:	None

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1. Description of the Device

The Syntec Orthodontic Mini Screw Extended System is a modification of our own device Syntec Orthodontic Mini Screw (K090476).

2. Indications for Use

This Syntec Orthodontic Mini Screw Extended System is intended to provide fixed anchorage for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. They are used temporarily and are intended to be removed after orthodontic treatment has been completed. The screws are intended for single use only.

3. Technological Characteristics Comparison to Previous Device

The Syntec Orthodontic Mini Screw Extended System is substantially equivalent (SE) to the predicate. The indications for use for this system are unchanged from the clearance of our predicate device, K090476. The screws are fabricated from stainless steel (SUS316L) per ISO 5832-1:2007/ASTM F138-13 and Titanium-6 Aluminum-4 Vanadium Eli (Extra Low Interstitial) Alloy per ISO 5832-3:1996/ASTM F136-13 as same as previous devices (K090476).

This minor change device system in its final finished form is identical to Syntec Orthodontic Mini Screw (K090476) in formulation, processing, and sterilization and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents). The modifications included in the subject submission are a change to the screw hole type, from the previously cleared circular design, to a rectangular shape. A brief summary of the technological characteristics of the minor change device in comparison to those of the predicate device as below table:

ø1.5 Small Mushroom Style

	Subject device	**Predicate Device**
Device Name	Syntec Orthodontic Mini Screw Extended System	Syntec Orthodontic Mini Screw
Applicant	Syntec Scientific Corporation	Syntec Scientific Corporation
510(k)	K202790	K090476
Material Comparison	Surgical Stainless Steel (SUS316L) Surgical Titanium Alloy (Ti6AL-4V)	Surgical Stainless Steel (SUS316L) Surgical Titanium Alloy (Ti6AL-4V)
Screw Diameter	ø1.5	ø1.5

Pitch	0.68 mm	0.68 mm
Thread Height	0.25 mm	0.25 mm
Length	6~12 mm	6~12 mm
Neck Length	0.4 mm	0.4 mm
Hole Shape Style	Rectangular/Circle	Circle

ø2.0 Small Mushroom Style

Screw Diameter	ø2.0	ø2.0
Pitch	0.75 mm	0.75 mm
Thread Height	0.32 mm	0.32 mm
Length	6~12 mm	6~12 mm
Neck Length	0.4 mm	0.4 mm
Hole Shape Style	Rectangular/Circle	Circle

ø1.5 Large Mushroom Style

Screw Diameter	ø1.5	ø1.5
Pitch	0.68 mm	0.68 mm
Thread Height	0.25 mm	0.25 mm
Length	7~12 mm	7~12 mm
Neck Length and Hole Shape Style	0.7 mm with Circle 0.8mm with Rectangular 1.4 mm with Circle	0.7 mm with Circle

ø2.0 Large Mushroom Style

Screw Diameter	ø2.0	ø2.0
Pitch	0.75 mm	0.75 mm
Thread Height	0.35 mm	0.35 mm
Length	7~12 mm	7~12 mm
Neck Length and Hole Shape Style	0.7 mm with Circle 0.8mm with Rectangular 1.2 mm with Circle	0.7 mm with Circle

4. Summary of Performance Data (Nonclinical and/or Clinical)

***Clinical Test**

Clinical data and conclusions were not needed for these devices.

***Non-Clinical Test**

The Syntec Orthodontic Mini Screw Extended System was considered for conformance to dimensional and material mechanical property standards ASTM F138-13, F136-13 and ISO 5832-3. All items in the scope were in conformance with those standards.
The Syntec Orthodontic Mini Screw Extended System has been subjected to safety, performance, and product validations prior to release.

Safety tests including biocompatibility (FDA recognized standard: ISO 10993-1) have been considered to ensure the devices comply with the applicable International and US regulations. Analysis of the worst case for performance testing, including fracture load, rotational fracture torque, and axial pull-out strength (FDA recognized standard: ASTM 543), showed that the testing of the predicate device was appropriate to be leveraged for the subject device. Therefore, these tests were not repeated in this submission.

***Conclusions**

The analysis information presented in this submission demonstrates that the subject device is substantially equivalent to the predicate devices.

5. Substantial Equivalence

In conclusion, the Syntec Orthodontic Mini Screw Extended System has the same intended uses and indications and principles of operation to the predicate device. Performance testing showed that the device is not a new worst case in performance characteristics compared to the predicate. Thus, the Syntec Orthodontic Mini Screw Extended System is substantially equivalent in design, configuration, function, and indications for use to the previous own device.