1 of 2

510(k) SUMMARY

K090476

510(K) SUMMARY

Submitter's name : Syntec Scientific Corporation

Address : 2, Kung San Rd,
Chuan Shing Industrial Zone,
Shen Kang,
Chang Hua, Taiwan.
Telephone :886-4-7987099
Fax: 886-4-7987077

JUN 18 2009

Date the summary was prepared : April 25, 2008

Name of the device :	Syntec orthodontic mini screws
Trade or proprietary name :	Syntec orthodontic mini screws
Common or usual name :	Ortho Anchor Screws
Classification name :	Implants, Endosseous, Orthodontic
Prode Code :	OAT
Regulation No. :	872.3640
Class :	II

1. Description of the Device:

The screws are manufactured from commercially SUS316L （stainless steel）and Ti-6AL-4V （titanium alloy）. The screws are available with thread diameter are from 1.3mm to 2.0 mm, and total lengths from 5mm to 17mm. There is a pair of self-tapping flutes and self-drilling flutes for easy insertion and removal. The design of smooth curve surface of screw head is comfortable to patients, and the screws with or without a 0.65mm diameter hole can supply different orthodontic methods for orthodontists.

***2.* Indications for Use:**

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.

3.Substantial Equivalence :

The Syntec orthodontic mini screws have same intended use as the Leone Orthodontic Mini Implant from Leone SpA, 50 Via P. a Quaracchi Sesto, Fiorentino, IT-500 19, cleared 510（k） no. K071490, and have equivalent performance characteristics.

Device Name	Syntec orthodontic mini screws	Leone orthodontic mini implant
Product code	OAT	OAT
Regulation no.	872.3640	872.3640
Applicant	Syntec Scientific Corporation（Taiwan）	Leone SpA（Italy）
510（k）	This Submission	K071490
Intended use	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.	Provide a fixed anchorage for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. It is used temporarily in the maxillary and mandibular bone and must be removed after orthodontic treatment has been completed.
Material	Surgical stainless steel ISO 5832-1 Surgical titanium alloy ISO 5832-3	Surgical stainless steel ISO 5832-1
Sterility	Non-sterile. Steam sterilize before use.	Non-sterile. It is recommended to sterilize with steam autoclave before use.

4.Conclusion:

The Syntec orthodontic mini screws raises no new issues of safety or effectiveness. The Syntec orthodontic mini screws does not additional concerns regarding safety and effectivity and may therefore be considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2009

Ms. Susan Cheng
Syntec Scientific Corporation
3F1. 96 Chung Hsiao E. Road Section 3
Taipei
CHINA (TAIWAN) 106

Re: K090476
Trade/Device Name: Syntec Orthodontic Mini Screws
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: June 11, 2009
Received: June 16, 2009

Dear Ms. Cheng:

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.

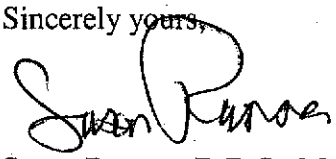
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/Centers_Offices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090476

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INDICATION FOR USE

Indications for Use

510(k) Number (if known):
Device Name: Syntec orthodontic mini screws
Indications for Use:

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.

Kevin Hurley for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090476

Prescription Use _____X_____ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)