November 15, 2019

GNI Co., LTD
℅ Sang Myung
Regualtory Affair Consultant
E&M Consulting
D-1474ho, 230 Simin-daero, Dongan-gu
Anyang, 14067 Kr

Re: K182672
Trade/Device Name: ROSA Bracket
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NJM
Dated: October 7, 2019
Received: October 19, 2018

Dear Sang Myung:

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 Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182672

Device Name
ROSA Bracket

Indications for Use *(Describe)*

This device is intended for the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be 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.

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

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510(k) Summary

K182672

This summary of 510(k) Safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter: GNI Co., LTD
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Date 510(k) summary prepared: October 7, 2018

Trade Name: ROSA Bracket
Common Name: Orthodontic Ceramic Brackets
Classification Name: Orthodontic plastic bracket
Classification: Class II
Product Code: NJM
Classification Panel: Dental
Regulation Numbers: 21 CFR 872.5470
Type of 510(k) submission: Traditional

Description of Device:

Orthodontic Ceramic bracket, ROSA Bracket is an orthodontic bracket attached to teeth to recover aesthetics and function of malocclusion. Made with aluminum oxide, it is attached to teeth and straightens irregular teeth with orthodontic wire installed through the wire's elasticity. It is made with aluminum oxide and seeks smooth movement of orthodontic wire for straightening irregular teeth and it requires additional rubber ring or ligating wire to fix Wire. It consists of three parts: the first part is the slot for the orthodontic wire; the second part is a round groove that is to hold a wire with an elastic "O" ring; the third part is the base that adheres to the tooth surface. A colored marking on wing part of bracket indicates orientation for placement.

Indication for use: This device is intended for the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be single use only

Predicate Device

Primary Manufacturer: Speed Dental Co., Ltd
510(k) Number: K150141
Trade Name: Orthodontics Bracket
Common Name: Orthodontic Ceramic Brackets
Regulation Name: Orthodontic Plastic Bracket
Regulation Numbers: 21 CFR 872.5470
Product Code: NJM
Classification: Class II

Substantial Equivalence:

Comparison table is as follows.

Table 1: Substantial equivalence comparison

Manufacturer	**GNI Co., LTD**	**Speed Dental Co., Ltd**
510(k)Number	K182672	K150141
Common Name	Orthodontic Ceramic Brackets	Orthodontic Ceramic Brackets
Trade Name	ROSA Bracket	Orthodontics Bracket
Indication for Use	This device is intended for the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be single use only	This device is intended for the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be single use only
Target Population	Patients in need of teeth alignment correction	Patients in need of teeth alignment correction
Material	Aluminum Oxide	Aluminum Oxide
Biocompatibility	Meets the applicable requirement of ISO 10993	Meets the applicable requirement of ISO 10993
Transparency	Half-transparency	Half-transparency
Design	Hook, Slot, Round home, base and marking	Hook, Slot, Round home, base and marking
Maxillary In-out(mm)	1.0 – 1.2	1.04 – 1.19
Maxillary Torque (°)	-7 to +17	-7 to +17
Maxillary Angulation	0 - 11	0 - 10
Slot Size	0.022 inch	0.022 inch
orientation marking	Colored dot on external surface	Colored dot on external surface
Single Use	YES	YES
Non-sterile	YES	YES

Information provided in these 510(k) submissions shows that ROSA Brackets are substantially equivalent to the predicate devices in terms of indication for use, device design and performance that related with technological characteristics.

Differences between the proposed and predicate devices are not expected to affect the overall performance of the device. These differences include slight variations in design such as maxillary angulation and In-Out. While the ranges are not identical, they are still within the range of what is typically observed for orthodontic brackets. These differences do not raise different questions of safety or effectiveness.

Biocompatibility testing:

Biocompatibility testing including cytotoxicity, sensitization, oral mucosal irritation was completed according to the following standards: ISO 10993-1 Biological Evaluation of Medical Devices –Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process ISO 10993-5 Biological Evaluation of Medical Devices – Part 5 Cytotoxicity ISO 10993-10 Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization ISO 10993-12 Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials

Non-clinical Performance Data:

Non-clinical performance testing was conducted as follows: design characteristics based on and in accordance with ISO 27020:2010 Dentistry – Brackets and tubes for use in Orthodontics; adhesive strength and analysis of detached teeth surface were conducted in accordance with ISO 11405:2015, Dentistry –Testing of adhesion to tooth structure; A risk analysis was conducted based on ISO 14971:2012 Medical devices – Application of risk management to medical devices.

Clinical Data:

No clinical performance testing was performed on ROSA brackets.

Conclusion

The Rosa Bracket has the same device characteristics as the predicate device, based on the information provided in this summary. We conclude that Rosa Bracket is substantially equivalent to the predicate device of Orthodontics Bracket. (K150141)