August 9, 2024

Genoss Co., Ltd
Jiyeon Lee
RA staff
1F, Gyeonggi R&DB Center, 105 Gwanggyo-ro, Yeongtong-gu,
Suwon-si, Gyeonggi-do
SOUTH KOREA

Re: K222688
Trade/Device Name: The Trust
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EKX
Dated: July 16, 2024
Received: July 16, 2024

Dear Jiyeon Lee:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K222688

Device Name
The Trust

Indications for Use *(Describe)*
The Trust is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region. The Trust is restricted to usage with Dentium implant system, and the angle of the Attack Pole to the abutment must be maintained at 90° when in use.

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

8/6/24

1. Company

	Submitter
Name	GENOSS Co., Ltd.
Address	Head Office: 1F, Gyeonggi R&DB Center, 105 Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea Manufacturing site: D-Factory, 56, Changnyong-daero 256 beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea
Phone/Fax	+82-70-7098-7573
Contact person	Jiyeon Lee / RA jylee3@genoss.com
Summary Date	8/6/24

2. Device Name

Proprietary name:	The Trust
Regulation description:	Dental Implant stability measuring device
Classification name:	Handpiece, Direct Drive, AC-Power

3. Predicate Device

K180953	AnyCheck IMT-100

4. Description

This equipment measures the time between the healing abutment and the striking rod by mechanically striking the implanted abutment and quantifies the fluctuation between the implant abutment and the alveolar bone. It is a principle to measure the contact time according to the acceleration change at the moment of being hit by using the acceleration sensor mounted on the Attack Pole. The higher the number, the better the fixation between the implant fixture and the bone.

5. Indication for use

The Trust is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region. The Trust is restricted to usage with Dentium implant system, and the angle of the Attack Pole to the abutment must be maintained at 90° when in use.

6. Comparison Technological Characteristics with the Predicate Devices

The Trust was compared to the predicate device, Anycheck IMT-100, from a technical, and biological perspective. The comparison of the predicate device to the subject device does not raise any new questions of safety and effectiveness. The reasons for this are shown in the table below.

Device name		The Trust	AnyCheck IMT-100
Manufacture		Genoss Co., Ltd.	DMS Co., Ltd.
510(K) Number		New device	K180953
Classification		Class I	Class I
Regulation Number		21 CFR 872.4200	21 CFR 872.4200
Classification Product Code		EKX	EKX
Clinical	**Target population**	Human Tooth	Human Tooth
	Indication for use	The Trust is restricted to usage with Dentium implant system, and the angle of the Attack Pole to the abutment must be maintained at 90° when in use.	The AnyCheck IMT-100 is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region
	Performance Property	The Trust measures the time when the rod hits the installed implant base by mechanically vibration, and quantifies the stability of the implant. The contact time is the principle of measuring the contact time according to the change in the acceleration of the moment struck using the accelerometer mounted on the strike rod. The higher the number, the implant stability is more rigid.	AnyCheck measures the time when the rod hits the installed implant base by mechanically vibration, and quantifies the stability of the implant. The contact time is the principle of measuring the contact time according to the change in the acceleration of the moment struck using the accelerometer mounted on the strike rod. The higher the number, the implant stability is more rigid.
	Anatomical Location of Use	Implant or Abutment	Implant or Abutment
	Anatomical Sites	Root canal, Softened dentin	Root canal, Softened dentin
Technical	**Error of measurement value**	±3 ISV	±3 IST
	Angle deviation	Alarm sounds when out of angle of use (Setting angle 0~90◦)	Alarm sounds when out of angle of use (Setting angle 0~30◦)
	Size and Weight	Instrument size: 220 x 25 x 27.5 mm Instrument weight: 80g	Instrument size: 195 x 31.8 mm Instrument weight: 100g
	Electrical Rated Voltage/ Current	DC 3.7V / 0.5A	DC 5V / 1A
	Auto Power off	120sec (±10%)	60sec
	Tapping Strength, Times	Under 3N 7 times 0.3 sec / 1 time	Less than 1.3N 6 times 0.5 sec / 1 time

	Components	Front Housing Attack Pole Body – Power and operation button, LCD window USB Connector USB C-type Cable	AnyCheck Main Body Tapping Rod Tapping Rod Front Guide ON/OFF Switch LCD Display Target Bar Tapping Rod Allen Wrench USB C Type Cable
	Rated Voltage	DV 5V (USB C-Type)	DV 5V (USB C-Type)
	Operation Mode	Continuous Operation	Continuous Operation
	Display	Power ON display Operation display Start Charging display ISV scale display (1~99) Operating Error display Charging error display	ON/OFF display Operation display Charging display IST scale display (0~99), Error display (Error)
	Commands/ Function	Power ON Measurement Power OFF	Power ON Action Power OFF
	Mechanical/ Electrical safety/ Standards	The Trust is designed and manufactured with applicable standards: IEC 60601-1	AnyCheck is designed and manufactured with applicable standards: IEC 60601-1
Biological	**Chemical Safety**	Biocompatible	Biocompatible
	Cytotoxicity/ **Oral mucosa irritation/** **Skin sensitization**	According to ISO 10993-5 ISO 10993-10 ISO 10993-12	According to ISO 10993-5 ISO 10993-10 ISO 10993-12
	Sterilization	User sterilization and disinfection	User sterilization and disinfection

6.1 Gap Analysis

Gap (1): Accessories for measurement of stability

There are differences in the components of the subject device and the predicate device, but those differences do not affect the safety and effectiveness of this product.

-Tapping Rod: The tapping rod of the predicate device is a component that plays the same role as the attack pole of the subject device, and is a component that measures the stability of the implant by tapping the healing abutment.

-Front Guide Tapping Rod: The Front Guide Tapping Rod in the predicate device is a component that guides the movement of the tapping rod to measure implant stability, and the Front Housing in the subject device performs the same role. Therefore, there are no issues with the safety and effectiveness of the product.

Gap (2): Discussion of the similarities

-Technical: Both the predicate and subject devices are utilized on the implant abutment to measure contact duration by striking it, expressing implant stability numerically. These products are deemed equivalent as they operate on the same principle at the same site.

-Biological: Both the predicate and subject devices are medical devices with components that contact the body. Biological evaluation requirements for both products adhere to the FDA-recognized ISO 10993 consensus standard, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing." Therefore, there are no concerns regarding the safety and effectiveness of the product.

Gap (3): Discussion of the difference

Predicate device has a component called a target bar to ensure the accuracy of measurements. Subject device does not include this component. Instead, we included a calibrator within the subject device. Subject device derives measurement values by calculating the contact time between the abutment and the Attack Pole, but when operating in the air, its movement is stopped by a component called a Collar spacer. Because the attack pole does not touch the object, contact time cannot be calculated. Therefore, the measurement will be 0 and the user can assume that the machine is operating normally. Therefore, if the measured value is displayed as 0 when operating in the air, it is operating normally. In conclusion, a calibrator like the Target Bar on the predicate device is built into the subject device.

In the case of predicate device, the tapping rod and the main body are connected by screwing, so an Allen wrench is used to ensure a firm connection. However, in the case of subject, the Attack Pole and the body are connected by magnets, so there is no need for separate connection parts. This difference in parts does not affect the effectiveness or safety of the product.

7. Biocompatibility Data

Biocompatibility testing on the proposed The Trust has been completed. Requirements for biological evaluation of the proposed device were based on FDA recognized concensus standard of ISO 10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing." The biocompatibility test results show that the materials used in the design and manufacture of the components of the proposed device are non-toxic and non-sensitizing to biological bone and tissues with its intended use.

8. Performance Data

All test results show that the materials, manufacturing processes and design used in The Trust met established specifications required for consistent performance for the intended use. Additionally, performance comparison tests with already licensed products confirm that the two products have similar performance (refer to 002_Equivalence test to AnyCheck). Therefore, there is no effect on the safety or effectiveness of this device.

9. Conclusion

Based on the information provided in this premarket notification of GENOSS Co., Ltd. concluded that comparing the two devices does not raise new questions about safety and effectiveness.