Rgorithm Korea
% Sanglok Lee
Manager
Wise Company Inc.
#507, #508, 166 Gasan digital 2-ro
Geumcheon-gu, Seoul 08503
Korea, South

7/18/2023

Re: K221107
Trade/Device Name: TRUST
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: PNP
Dated: June 29, 2023
Received: June 30, 2023

Dear Sanglok 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 (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,

Sherrill Lathrop Blitzer

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)*
K221107

Device Name
TRUST

Indications for Use *(Describe)*
TRUST is intended as an aid to the restoration of chewing function in partially edentulous mandibles and maxillae. TRUST is a software device intended to be used by a dental practitioner or dental laboratory staff for designing the patient specific component of one-piece type abutment. The design result is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – Traditional 510(K)

The assigned 510(k) Number: K221107

01. Date of Submission: July 17, 2023

02. Applicant / Submitter

Rgorithm Korea
A-1502, 606 Seobusaet-gil, Geumcheon-gu, Seoul, 08504, Republic of Korea
Tel. +82 2 6264 4688

03. Submission Correspondent

Sanglok, Lee
Wise COMPANY Inc.
#507, #508, 166 Gasan digital 2-ro, Geumcheon-gu, Seoul, Korea
TEL: +82 2 831 3615
Email: info@wisecompany.org

04. Proposed Device Identification

Device Identification and Regulatory information

Proprietary Name: TRUST
Common Name: Dental Abutment Design Software For Dental Laboratory
Device Class: Class II
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Product Code: PNP

Indication for use: TRUST is intended as an aid to the restoration of chewing function in partially edentulous mandibles and maxillae. TRUST is a software device intended to be used by a dental practitioner or dental laboratory staff for designing the patient specific component of one-piece type abutment. The design result is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

05. Predicate Device Identification

- Predicate device
510(k) Number: K200100
Device Name: Abutment Design
Manufacturer: 3Shape A/S

06. Device Description

TRUST is intended as an aid to the restoration of chewing function in partially edentulous mandibles and maxilla. TRUST is a software device intended to be used by a dental practitioner or dental laboratory staff for designing the patient specific component of one-piece type abutment. The design result is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

TRUST is restricted to be used with 510(k) cleared abutment systems, and the design output from TRUST (the patient specific part of the abutment) must be manufactured according to the instruction of the selected Implant system.

TRUST includes design parameters from the 510(k) cleared abutment systems such as implant type, maximum and minimum dimensions (e.g., abutment post height, gingival height, angulation, gingival margin diameter, wall thickness). The design parameters, provided by abutment system manufacturers(Truabutment), for an abutment system are available via a Trust server when documentation of the 510(k) clearance of said implant system is confirmed by Rgorithm.

TRUST has no patient contact being a software only device. (stand-alone software)

Scientific Concept
The underlying scientific concept of TRUST is to apply digital imaging tools for computer aided design(CAD) of abutments.
The system supports the following types of digital data: STL and PLY Only(3D surface data)

07. Summary of Technological Characteristics Comparison

TRUST has the same intended uses, principle of operation and similar technical characteristics and

	Subject Device	Predicate Device	Substantial Equivalence
Device Name	TRUST	Abutment Design	-
510K number		K200100	-
Classification	Class 2	Class 2	Equivalent
Intended use	TRUST is intended as an aid to the restoration of chewing function in partially edentulous mandibles and maxillae. TRUST is a software device intended to be used by a dental practitioner or dental laboratory staff for designing the patient specific component of one-piece type abutment. The design result is intended to be used by the manufacturer of an	Abutment Design is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. Abutment Design is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece, or hybrid dental implant abutment. The resulting abutment design is intended to be used by	Substantially Equivalent Discussion – Intended use of the subject device is a subset of the predicate device's Intended use, and the inclusion of 'fully edentulous' or not does not raise any questions of substantial equivalence. Discussion - The change in allowable abutment types does not raise any questions of substantial equivalence.

	endosseous dental implant abutment to create the final device.	the manufacturer of an endosseous dental implant abutment to create the final device	
Hardware requirements			
OS	Windows 7, 8, 10 (64-bit)	Windows 7, 8, 8.1 or 10 (64-bit)	Equivalence
RAM	16GB	8 GB	Equivalence or higher
Monitor Resolution	1920X1080 pixels	1920x1080 pixels	Equivalence
Video Card Memory	DirectX 11	1GB DirectX 11	Equivalence
Available HDD Space	500 GB (1TB if used as a standalone system or a server with the order folder)	500 GB (1TB if used as a standalone system or a server with the order folder)	Equivalence
CPU	Intel I3 Dual core	Intel Core i7 or equivalent	Equivalence or lower
Network	Network Internet connection	Network Internet connection	Equivalence
USB ports	Software only	USB 2.0 port for 3Shape desktop scanner	Not Equivalence No additional connection required
Mouse	With the wheel button support	With the wheel button support	Equivalence
3D Mouse	Including wheel control mouse	(Optional) 3DConnexion SpaceMouse™ Pro	Not Equivalence It only supports normal keyboards and mouse.
Feature			
Graphical UI	Yes	Yes	Equivalence
Windows OS platform	Yes	Yes	Equivalence
Uses standard PC hardware	Yes	Yes	Equivalence

Digitally imports topography of teeth by 3D Scan	Yes	Yes	Equivalence
Uses 3D CAD design tools	Yes	Yes	Equivalence
Patient specific abutment design	Yes	Yes	Equivalence
Implant Bar design	No	No	Equivalence
Export to remote milling machine by internet	Yes	Yes	Equivalence
Network Protocol	Internet/TCP-IP	Internet/TCP-IP	Equivalence
Intended users	Dental practitioners and dental technicians	Dental practitioners and dental technicians	Equivalence
Output type	The abutment is saved as a .TMZ file. Digital encrypted proprietary .TMZ file only of the patient specific abutment component, not including the abutment-to implant connection interface. Encryption is always active until the output is decrypted by our servers during the ordering process, when it is sent to an abutment manufacturer for creation of the final	Digital encrypted or non-encrypted proprietary or .STL file only of the patient specific abutment component, not including the abutment-to implant connection interface. If encryption is active or not will solely be determined by the 510(k) clearance of the abutment system.	Equivalence

	device.		
*Device submission includes pre-manufactured prosthetics	No	No	Equivalence

Abutment Design (K200100) is bundled with Intra-oral Scanner or model scanner. Trust is stand-alone and Web distribution S/W. Abutment Design(K200100) manages licenses in a USB dongle, while Trust manages licenses in the web.

The difference in use of a USB dongle compared to the subject license management in the web is addressed by cybersecurity measures which use the IP address to verify user's ID and password.

08. Non clinical Testing Data

Software, hardware, and integration verification and validation testing was performed in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", issued on May 11, 2005.

The validation suite includes validation of implemented mitigations related to device hazards identified in the risk management procedures.

The cybersecurity analysis was performed in accordance with the FDA Guidance Document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", issued on October 02, 2014.

All test results have been reviewed and approved, showing the TRUST to be substantially equivalent to the primary predicate device.

09. Clinical Testing

Clinical testing is not a requirement and has not been performed.

10. Substantial Equivalence Conclusion

Based on the results of software validation and the information provided herein, we conclude that the proposed device is substantially equivalent to the predicate devices.