DMS Co., Ltd.
% Soojung Moon
Consultant
Allura Medical Solution, Inc.
8141 Lampson Ave.
#4
Garden Grove, California 92841

February 20, 2019

Re: K180953
Trade/Device Name: AnyCheck IMT-100
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EKX
Dated: January 15, 2019
Received: January 18, 2019

Dear Soojung Moon:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.02.20 18:26:54 -05'00'

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K180953

Device Name
AnyCheck IMT-100

Indications for Use *(Describe)*
The AnyCheck IMT-100 is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region.

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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510(k) Summary K180953

Submitter	DMS Co., Ltd. #201, #202 & #204, Oriental Medical Industry Development Center, Sangji University, 83, Sangjidae-gil, Wonju-si, Gangwon-do, 26339 Republic of Korea Phone. +82-33-742-3210 Fax. +82-33-742-3219
Contact Person	HWI JOON PARK 8141 Lampson Ave. #4, Garden Grove, CA 92841, USA Phone: +1-972-800-0044 Fax: +1-210-899-0079
Submission Date	Jan 18, 2019
Trade / Proprietary name	AnyCheck IMT-100
Common / Usual Name	Dental Implant Mobility Measuring Instrument
Classification Name Classification Code Regulatory Class Regulation Number	Handpiece, Direct Drive, AC-Power EKX Class I 872.4220
Predicate Device	Osstell® ISQ Implant Stability Meter (Osstell AB) (K082523 – Primary predicate) Osstell® IDx (Osstell AB) (K142358 – Reference predicate) Tellos ISQ Buddy (Tellos Medical AB) (K143445 – Reference predicate)
Description of Device	The AnyCheck IMT-100 Dental Implant Mobility Measuring Instrument is a system designed to measure dental implant mobility (stability) in the oral cavity and maxillofacial region. The AnyCheck IMT-100 is a portable, handheld instrument to observe non-invasively the fixation stability of an implant at alveolar bone. The implant stability test (iST) is performed using vibration generated by mechanical contacting of a tapping rod. The AnyCheck IMT-100 numerically indicates a scale result of iST. The higher number means better stability of the target implant.
Indication for Use	The AnyCheck IMT-100 is indicated for use in measuring the stability of implants in the oral cavity and maxillofacial region.

Comparison of Technological Characteristics with the Predicate Devices	**Comparison of Indication for Use** The AnyCheck IMT-100 and the predicate devices have identical indications for use statements. **Materials** ABS, PEEK, Titanium Alloy, Aluminum, Silicon, polycarbonate resin, Accetal, Trimrite, Stainless Steel. **Design** The subject device has no "device setup menu", which is similar to Tellos ISQ Buddy (K143445), while other predicates need various parameters to set up before use. The weight and power scale of the subject device is within the range of all the predicate devices (3~ 12VA). **Technological Characteristics** The result of the measurement of the subject device and all other predicate devices is calculated from the resonance frequency. For measuring, predicate devices (K082523 and K142358) can be attached either to the implant or abutment, while the subject device should be attached only to the abutment. But the performance data shows the output values between the subject device and the predicate devices are similar and the difference is negligible. Also, OLED display does not raise any issues or concerns of safety and effectiveness for the use of the subject device, compared to the predicate devices which use LED or LCD display. **Clinical Tests** This submission does not include clinical performance data, similar to the predicate devices. **Non-clinical Tests** Non-clinical testing was performed and comparative performance testing was conducted in order to validate the product against the company's specified design requirement. Measurement accuracy, output scale, reproducibility and electrical safety tests according to IEC60601-1 were performed. Also, cytotoxicity, oral mucosa irritation and skin sensitization test were conducted with respect to biocompatibility according to ISO 10993-5, ISO 10993-10 and ISO 10993-12. The laboratory certified that the insolubility is in compliance with the requirements of the standard. There is no evidence that effects hazardous to the patient will arise by leachable ingredients/contaminants.
Conclusion	Based upon the similarities of indications for use, and similarities in technological characteristics, including materials and design, together with the results of non-clinical performance testing, we find that the AnyCheck IMT-100 Dental Implant Mobility Measuring Instrument is substantially equivalent to the predicate devices.