May 6, 2022

Rayence Co.,Ltd
Dave Kim
Medical Device Regulatory Affairs
Mtech Group
7505 Fannin St. Ste 610
Houston, Texas 77054

Re: K220689
Trade/Device Name: Vatech Clismile
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NJM
Dated: February 28, 2022
Received: March 9, 2022

Dear Dave Kim:

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,

Michael E. Adjodha, M.ChE.
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)*

K220689

Device Name
Vatech Clismile

Indications for Use *(Describe)*
Vatech Clismile is indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.

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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K220689

510(k) Summary

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

Date 510k summary prepared: January 28th, 2022

Submitter's Name, address, telephone number, a contact person:

Submitter's Name :	Rayence Co., Ltd.
Submitter's Address:	14, Samsung 1-ro 1-gil, Hwaseong-si, Gyeonggi-do, Korea
Submitter's Telephone:	+82-31-8015-6459
Contact person:	Mr. Kee Dock Kim / RA Team Manager / +82-31-8015-6459
Official Correspondent:	Dave Kim **(**davekim@mtech-inc.net**)**
Address:	7505 Fannin St. Ste 610-V111, Houston, TX 77054
Telephone:	+713-467-2607

Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Trade/proprietary name	**:** Vatech Clismile
Common Name	: Orthodontic ceramic bracket
Regulation Number	: 21 CFR 872.5470
Regulation Name	: Bracket, Ceramic, Orthodontic
Regulatory Class	: Class II
Product Code	: NJM(Orthodontic plastic bracket)

Predicate Device :

Trade/Device Name	: In-Ovation C
Common Name	: Orthodontic ceramic bracket
510(k) Number	: K060837
Regulation Number	: 21 CFR 872.5470
Regulation Name	: Bracket, Ceramic, Orthodontic
Regulatory Class	: Class II
Product Code	: NJM

2. Device Description

This product is an orthodontic bracket and is used with orthodontic wire materials and other orthodontic products to treat malocclusion of the upper and lower teeth.

It is used to correct teeth by transmitting physical force to each tooth, and is a self-ligation bracket using a ceramic body and a metal cap made of a metal material. Shelf-life is not applicable because of the low likelihood of time-dependent product degradation.

3. Indication for use

Vatech Clismile is indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.

4. Summary of Design Control Risk management

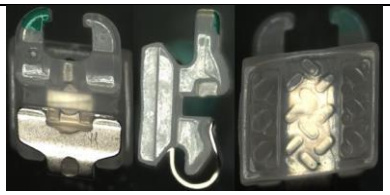
Vatech Clismile orthodontic brackets were developed with the same structure, material / operation method, and purpose as In-Ovation C.

The risks and the hazardous impact of the device modification were analyzed with FMEA method. The specific risk control and protective measures to mitigate the risks from the modification were reviewed and implemented in the new product design phase. The overall assessment concluded that all risks and hazardous conditions identified arising from the design change were successfully mitigated and accepted.

5. Summary of the technological characteristics of the device compared to the predicate device:

Vatech Clismile described in this 510(k) has the same indications for use and similar technical characteristics as its predicate devices, IN-OVATION C (K060837).

Comparison table

Characteristic	Proposed Device	Predicate Device	Similarity
Manufacturer	**Rayence CO., LTD**	**DENTSPLY International**	-
Product Name	**Vatech Clismile**	**IN-OVATION C**	-
Picture			Similar
510(k) number	**K220689**	**K060837**	-
Indications for use	Vatech Clismile is indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.	In-Ovation C is indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.	Same
Material composition of Bracket	Polycrystalline Alumina(100%)	Polycrystalline Alumina(100%)	Same
Material composition of Door	Nikel-Cobalt Alloy(100%)	Nikel-Cobalt Alloy(100%)	Same
Transparency	Half-transparency	Half-transparency	Same
Bracket design	MBT, ROTH designs with and without hook, conforming to ISO 27020:2010 Dentistry – Brackets and tube for Use in Orthodontics	MBT, ROTH designs with and without hook, conforming to ISO 27020:2010 Dentistry – Brackets and tube for Use in Orthodontics	Same
Self-ligating mechanism	Yes	Yes	Same
Orientation marking	Yes	Yes	Same
Non-sterile packaging	Yes	Yes	Same
In-out(mm)	1.05 to 1.54	1.05 to 1.55	Same
Torque(◦)	-11 to +17	-11 to +17	Same
Angulation(◦)	0 to 13	0 to 13	Same
slot sizes	0.022 inch	0.018" / 0.022 inch	Similar

6. Summary of Performance Testing

IN-OVATION C and Vatech Clismile have the same composition and raw material of the components constituting the device, and the purpose and principle of operation of the calibration bracket are the same. Bracket generally uses a one-kit product consisting of 20 brackets. The K100-552-81 model of In-Ovation-C is composed of 16 ceramic and 4 metal brackets, and the Clismile is also composed of the same number of sets.

The ceramic bracket is composed of alumina (Body) and Ni-Co alloy (Cap, MP35N)

The design characteristics of the product were evaluated for seven items specified in ISO 27020, which is a bracket standard. As representative products, dimensional analysis of "Clismile 12-1223" and "IN-OVATION C H100-132-81" corresponding to the maximum canine was conducted, and it was confirmed that the dimensions were the same within the error range.

7. Summary for any testing and reference guidance:

- Dimension evaluation of prescription of orthodontic bracket according to standard ISO27020 (Brackets and tubes for use in orthodontics)
- Evaluation report on biological stability according to standard ISO10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity, ISO 10993-10 Biological evaluation of medical devices — Part 10: Tests for skin sensitization,), ISO 10993-11 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
- Evaluation of hazardous element content and corrosion test for metal cap bracket parts according to standard ISO 22674(Metallic materials for fixed and removable restorations and appliances)

8. Conclusions:

In accordance with the performance outcomes, Vatech Clismile demonstrated equivalent performance compared to In-Ovation-C. Therefore, Rayence claims the substantial equivalency between the proposed device and predicate device in terms of safety and effectiveness.