April 21, 2025

EC Certification Service GmbH
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K251196
Trade/Device Name: Composite Orthodontic Brackets and Buttons
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: DYW
Dated: April 17, 2025
Received: April 17, 2025

Dear Prithul Bom:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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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.

Submission Number *(if known)*

K251196

Device Name

ECC Premium Line

Indications for Use *(Describe)*

The intended use of composite brackets and buttons is to be bonded to the teeth to provide orthodontic movement of natural teeth.

The main indication for use of orthodontic brackets and buttons is a malocclusion, such as misaligned teeth, overcrowding, spacing issues, and bite irregularities.

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.

510(k) #: K251196

510(k) Summary

Prepared on: 2025-04-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	EC Certification Service GmbH
Applicant Address	Sandgasse 39a Sankt Veit an der Glan AT 9300 Austria
Applicant Contact Telephone	+4342126094
Applicant Contact	Mrs. Elisabeth Moschik
Applicant Contact Email	office@ec-c.at

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ECC Premium Line
Common Name	Composite Orthodontic Brackets and Buttons
Classification Name	Bracket, Plastic, Orthodontic
Regulation Number	872.5470
Product Code(s)	DYW

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K973776	Reflections	DYW

Device Description Summary

21 CFR 807.92(a)(4)

Composite orthodontic brackets and buttons present a clear and aesthetically pleasing choice for orthodontic patients undergoing orthodontic treatment. The Composite Bracket and Button is engineered to offer simple and aesthetic devices that address both minor and complex misalignments in patients.

Composite orthodontic brackets and buttons are classified as Class II medical devices. In accordance with ISO 10993-1:2018, based on the nature of body contact, orthodontic brackets and buttons are categorized as having mucosal contact, as they are affixed to the teeth and maintain prolonged contact with the oral mucosa. Furthermore, the contact duration is categorized as "permanent exposure" (=more than thirty days), as brackets and buttons are expected to remain in place for extended periods during orthodontic treatment.

Utilized by orthodontic professionals, these brackets and buttons serve as integral components - together with adhesives, wires, bands, elastics and other attachments in the alignment and correction of dental malocclusions and misalignments. The duration of the treatment depends on the degree of misalignment and is between 6 months and a maximum of 2,5 years.

Brackets and buttons are strategically placed and affixed to the surface of the teeth using dental adhesive. This bonding process ensures that the brackets and buttons remain securely attached to the teeth throughout the orthodontic treatment. Then Orthodontic arch wires are pushed into the slot of the bracket. The slot acts as an aid to hold and guide the orthodontic wires that - in conjunction with elastic bands and other orthodontic accessories - exert gentle forces to the teeth, gradually, moving them into their desired position. These direct and indirect orthodontic bonding techniques with orthodontic adhesives is thoroughly documented in orthodontic literature. These additional products required for orthodontic treatment are chosen by the orthodontist as required and are hence not part of this 510(k) application. The removal of the brackets/buttons follow standard procedures that do not require additional training.

Composite Orthodontic Products are only to be used by Orthodontists/Dentists. As educated specialists they know exactly how to use

brackets and buttons. They have received training in order to analyse and decide with which other products they are best compatible (wires, adhesives, elastics and instruments). This 510(k) application is only for composite orthodontic brackets and buttons.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The intended use of composite brackets and buttons is to be bonded to the teeth to provide orthodontic movement of natural teeth.

The main indication for use of orthodontic brackets and buttons is a malocclusion, such as misaligned teeth, overcrowding, spacing issues, and bite irregularities.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The main predicate device "K973776" states following as intended use/Indications for Use: "
Orthodontic brackets are usually cemented to the front surface of the tooth where they direct the mechanical forces that urge teeth into correct alignment. A curved arch wire that is bent or twisted to a particular prescription before installation is forced into a slot in each bracket. The resulting torque or restoring force causes the teeth to shift into the desired alignment. Depending on the shape and twist of the arch wire and the orientation of the bracket slot, it is possible to apply forces, which can shift, rotate, or tip the teeth in any desired direction.
Stainless steel, ceramic and plastic brackets are in common use. Plastic brackets are more aestetically pleasing than the stainless steel which give a metallic smile. They are less expensive than ceramic."

The Intended Use is substantially Equivalent. The explanation provided for the predicate in its 510k application indicates through its explanation that the intention of the medical device is to create tooth movement ("….force causes the teeth to shift into the desired alignment"). Hence ECC and CDB share this intended use.

Technological Comparison

21 CFR 807.92(a)(6)

The FDA Guidance "510(k) Programm: Evaluating Substantial Equivalence in Premarket Notifications (510(k))" was consulted on the topic of Substantial Equivalence.
Brackets and Buttons from EC Certification Service fulfill the same technological characteristics as the predicate device from CDB Corp (K973776) regarding:
Design: All brackets do have a bracket body with low profile, possibility for hooks on cuspids and bicuspids, a mechanical retention base eleminating the need for plastic condition pretreatment, a slot to place wires, Torque / Angulation and Rotation values according defined prescriptions. Products do not show significant differences that would suggest one bracket type outperforms another in terms of technical specifications.
Orthodontic buttons are single wing brackets without torque, angulation, rotation and hook. Some of them have a slot to place wires.

Material and Chemical composition: The subject devices as well as the predicated ones are made of Polyurethane – which is a Composite / Plastic material and ensures an
esthetic look.

The Categorization of Medical Devices according to ISO 10993-1:2018 is the same.

The patient and tissue contact materials is in both cases biocompatible plastic (polyurethane).

Clinical characteristics: All Orthodontic Brackets and buttons show same clinical conditions, intended use, principal of operations, are used in the same site in the body, are in contact with the mucosa for the same duration and effect the same population.

The subject device, compared to the predicate device do not raise any issues of safety and effectiveness.

The comparison concludes that the ECC Premium Line is same or substantially equivalent in all areas of question.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

A series of bench tests were completed to show that the medical devices function as intended and meet the specified performance characteristics, as well as to ensure that the medical device does not pose a risk to the user or patient. The following tests were completed: Dimensional test, Hardness test, Shear Test, Friction Force Test, Gate Pull Test, Torque Test, Wear Abrasion Test, Water Absorption Test and Discoloration Test.

The dimensional test was done according to ISO 27020:2019 (FR 4-313).
Also the FDA Guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions" was taken into consideration.

No animal studies or clinical testing were required for these devices.

The results of the performed tests demonstrate that the medical device functions as intended and meets the specified performance characteristics. Furthermore, they ensure that the medical device withstands the stresses encountered during use as well as that they do not pose a risk to the user or the patient. Thus, the device is equally safe, effective, and performs as well as its predicate.