December 29, 2025

Celebrace
Sarah Moss
Regulatory Affairs Consultant
5708 Colleyville Blvd., Suite A
Colleyville, Texas 76034

Re: K253343
Trade/Device Name: Celebrace Software
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN
Dated: September 19, 2025
Received: September 30, 2025

Dear Sarah Moss:

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.

510(k) Number *(if known)*
K253343

Device Name
Celebrace Software

Indications for Use *(Describe)*
Celebrace software is a software designed to assist dental professionals in planning patient treatment and designing treatment devices. The software performs simulations based on patient images, allowing reference to treatment plans, and is used as a tool to design treatment devices based on 3D mesh data. Treatment devices include orthodontic devices (orthodontic wires, orthodontic brackets and bonding trays).

To use Celebrace Software, users must have the necessary education and domain knowledge in orthodontic practice and receive dedicated training in the use of the software.

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) #: K253343

510(k) Summary

Prepared on: 2025-12-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Celebrace
Applicant Address	5708 Colleyville Blvd., Suite A Colleyville TX 76034 United States
Applicant Contact Telephone	281-795-1812
Applicant Contact	Ms. Sarah Moss
Applicant Contact Email	smoss@primepathmedtech.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Celebrace Software
Common Name	Orthodontic plastic bracket
Classification Name	Orthodontic Software
Regulation Number	872.5470
Product Code(s)	PNN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233625	Raydent Software	PNN
K232429	Titan Dental Design	PNN
K203442	Inbrace Orthodontic Syste	PNN

Device Description Summary

21 CFR 807.92(a)(4)

Celebrace software is a software only device that creates an orthodontic treatment plan. The input to Celebrace Software are a combination of Intraoral Scans, CBCT radiographs and patient demographics. The output of the Celebrace Software is a treatment plan, which is approved by the treating dentist, and files used for physical manufacturing of the orthodontic devices (orthodontic wires, brackets and bonding tray). The software is powered by a static algorithm that is locked at the time of release.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Celebrace software is a software designed to assist dental professionals in planning patient treatment and designing treatment devices. The software performs simulations based on patient images, allowing reference to treatment plans, and is used as a tool to design treatment devices based on 3D mesh data. Treatment devices include orthodontic devices (orthodontic wires, orthodontic brackets and bonding trays).

To use Celebrace Software, users must have the necessary education and domain knowledge in orthodontic practice and receive dedicated training in the use of the software.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Celebrace software system outputs treatment device designs for orthodontic wires, brackets and indirect bonding trays. The predicate device outputs treatment device designs for prosthetic devices (Veneer, Crown, Bridge, In/Onlay) and orthodontic devices (Clear Aligner). The reference device output treatment device designs for bonding trays and clear aligners. The subject device creates 2D and 3D outputs, while the predicate device and reference device only output 3D designs.

Technological Comparison

21 CFR 807.92(a)(6)

Based on the above comparisons, the design, construction, and performance characteristics of the Subject Device are similar to that of the Predicate Devices.
The differences identified are not substantial differences in operation of the device.
Technological Features: Celebrace software system does not design prosthetics. This difference does not impact the efficacy of the software.

Analysis Features: Celebrace software system does not perform tooth segmentation. The segmentation of the teeth is done using a 510(k) cleared segmentation software (K233925). This difference does not impact the efficacy of the software and does not introduce any new risks.

OS/Hardware/IT Requirements: The differences between the predicate and subject device account for differences in the operating environment, but do not impact the intended use or application of the devices.
There are no other substantial differences between the technical requirements between the Subject and Predicate Devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The Subject Device has passed testing for appropriate verification and validation and performed per its intended use.

Software documentation was prepared per the recommendations of FDA Guidance Document, "Content of Premarket Submissions for Device Software Functions (Issued on June 14, 2023)," and ANSI/AAMI/IEC 62304: Medical Device Software - Software life cycle processes.

Based on the performance testing and software validation testing, the Subject Device, Celebrace Software, has been shown to be appropriate for its indications for use and is as safe and as effective as the legally marketed Predicate Device, Raydent SW (K233625). There are no substantial differences between the indications for use, technological features, or performance testing of the Subject and Predicate Device.