DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 27, 2016

CDB Corporation
Yannire Thompson
Quality & Regulatory Affairs Manager
9201 Industrial Boulevard, NE
Leland, North Carolina 28451

Re: K160957
Trade/Device Name: CDB Self Ligating Bracket 8F
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NJM
Dated: August 31, 2016
Received: September 1, 2016

Dear Yannire Thompson:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Ryan -S

for 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

Indications for Use Statement

510(k) Number (if known): K160957/S002

Device Name: CDB Self Ligating Bracket 8F

Indications for Use:

The CDB Self Ligating 8F bracket is indicated for orthodontic movement of uncompromised natural teeth, excluding mandibular bicuspid.

Prescription Use ___☑____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Submitter:	CDB Corporation 9201 Industrial Blvd, NE Leland, NC 28451 USA Phone: 910-383-6464 Fax: 888-280-1556 Contact: Yannire Thompson Title: Quality/Regulatory Affairs Manager Email: ythompson@cdbcorp.net
Date Prepared:	September 16th, 2016
Name of Device:	CDB Self Ligating Bracket 8F
Common Name:	Self Ligating Bracket
Classification Name:	Bracket, Ceramic, Orthodontic
Device Classification:	Regulatory class II Product code: NJM Classification Panel: Dental Regulation Number: 872.5470

Primary Predicate Device:

Company	Product	510(k)
Dentsply Int.	In-Ovation C	K060837

Device Description: CDB Self Ligating Bracket 8F is bonded to teeth to apply pressure to the tooth, transmitted through a flexible orthodontic wire to alter the tooth position. The modified orthodontic ceramic bracket has both aesthetic and self-ligating qualities. The modifications were aimed at facilitating easier orthodontic wire placement and removal through self-ligation and enhancing the bonding and debonding characteristic of the bracket.

Indications: The CDB Self Ligating 8F bracket is indicated for orthodontic movement of uncompromised natural teeth, excluding mandibular bicuspid.

Technical Characteristics:	The function, performance, and contact material of the CDB Self Ligating 8F is similar to the predicate. Minor design changes are the only modifications made to the In-Ovation C (K06083). There are no changes in the intended use and fundamental scientific technology. All of the materials used in the device have been used in legally marketed devices. We believe that the modified device is substantially equivalent to the predicate Orthodontic Ceramic Brackets In-Ovation C (K060837).
Performance Testing:	Comparative shear bond strength testing was conducted to the noted predicate device and that the results demonstrated that the bond strength was as strong as the predicate.
Physical Properties, Materials, Intended use Comparison:	The CDB Self Ligating Bracket 8F is identical in use, contact material type, manufacturing methods (injection molding, sintering, stamping, and plating), and duration of patient contact as the primary predicate device In-Ovation C (K060837). FDA requested to include here a table, similar to the one provided in the biocompatibility section, which compares the physical properties, materials, and intended use of The CDB Self Ligating Bracket 8F to the designated primary predicate device. Please find below a comparison for the primary predicate and the CDB Self Ligating Bracket 8F:

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		Primary Predicate
Property	**CDB Self Ligating Bracket 8F**	**Dentsply InOvation C**
Bracket Composition:	Aluminum Oxide	Aluminum Oxide Silicon Dioxide
Clip Material:	Nickel Titanium	Manganese Nickel Chromium Molybdenum Niobium Titanium Iron Cobalt
Clip Coating:	Gold Rhodium	Gold Rhodium
Intended Use:	Indicated for orthodontic movement of uncompromised natural teeth, excluding mandibular bicuspids.	Indicated for orthodontic movement of uncompromised natural teeth, excluding mandibular bicuspids.
Principles of Operation:	The wire is held in a passive, interactive, or active state by the clip. The clip slides into and out of place to ligate the wire.	The wire is held in a passive, interactive, or active state by the clip. The clip slides into and out of place to ligate the wire.
Aesthetic Features	Clear (translucent) bracket system	Clear (translucent) bracket system
Physical properties	Mechanical retention	Mechanical retention
Application	Bonded	Bonded
Manufacturing Method	Injection molding	Injection molding
Contact Classification	Permanent surface contacting device which contacts the mucosal membrane	Permanent surface contacting device which contacts the mucosal membrane
Color Additives	None	Unknown

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FDA requested to provide the name of another predicate device that has the same chemical composition as CDB Self Ligating Bracket 8F clip material. Please see below for two reference devices:

Click-it (K111234) by TP Orthodontics. Click-it is a self ligating ceramic bracket with a Nickel titanium clip.

Clarity SL (K062345) by 3M Unitek. Clarity SL is a self ligating ceramic bracket with a Nickel titanium clip.

Conclusion:

By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate devices.

There are no major differences between the CDB Self Ligating Bracket 8F and the predicate device cited; therefore the CDB Self Ligating Bracket 8F, as designed, is determined to be substantially equivalent to the referenced primary predicate device and reference devices currently on the market.

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