March 14, 2024

Prismatik Dentalcraft, Inc.
Jiahe Li
Sr. Regulatory Affairs Specialist
2144 Michelson Drive
Irvine, California 92612

Re: K231529
Trade/Device Name: CloudPoint FastDesign Chairside
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: PNP
Dated: February 12, 2024
Received: February 13, 2024

Dear Jiahe Li:

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.

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,

Andrew I. Steen -S

Andrew I. Steen
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)*
K231529

Device Name
CloudPoint FastDesign Chairside

Indications for Use *(Describe)*
CloudPoint FastDesign Chairside is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. CloudPoint FastDesign Chairside is intended for use by a dental practitioner or dental laboratory staff for designing the patient-matched component of a two-piece hybrid dental implant abutment. The resulting abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

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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PRISMATIK DENTALCRAFT, INC.

# 510(k) Summary

## I. SUBMITTER

Prismatik Dentalcraft, Inc.
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Date Prepared: March 13, 2024

## II. DEVICE

Name of Device: CloudPoint FastDesign Chairside
Classification Product Code: PNP
Regulatory Class: II
Common Name: Dental Abutment Design Software
Classification Name: Dental Abutment Design Software for Dental Laboratory (Endosseous Dental Implant Abutment 21 CFR 872.3630)

## III. PREDICATE DEVICE

Abutment Design (K200100)

## IV. DEVICE DESCRIPTION

CloudPoint FastDesign Chairside (also known as FastDesign), is a software suite intended to be used by trained dental practitioners or dental laboratory staff to design the patient-matched component of a two-piece hybrid dental implant abutment. A titanium base-type abutment and hybrid abutment-crown component are combined to make the two-piece hybrid dental implant abutment. The software allows a dental practitioner or dental laboratory staff to design the matching dental abutment based on imported scan data containing topographical characteristics of the patient's dentition. The resulting abutment design will be exported to a remote milling machine to make the final device.

CloudPoint FastDesign Chairside, is restricted to be used with 510(k) cleared abutment systems. The software includes design parameters from the 510(k) cleared abutment systems such as maximum and minimum dimensions (e.g., abutment post height[1], gingival height, angulation[2], gingival margin diameter, etc.). CloudPoint

FastDesign Chairside designs the endosseous dental implant abutment under the directions of a clinical professional and maintaining accordance to the requirements of the compatible 510(k) cleared abutment systems with cleared design parameter size ranges.

Notes:
1. Abutment post height is the height of the abutment post above the final gingival height design.
2. Angulation is the angle correction of the two-piece hybrid abutment off the axis of the implant placement.

## V. INDICATIONS FOR USE

CloudPoint FastDesign Chairside is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. CloudPoint FastDesign Chairside is intended for use by a dental practitioner or dental laboratory staff for designing the patient-matched component of a two-piece hybrid dental implant abutment. The resulting abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

PRISMATIK DENTALCRAFT, INC.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

| Technological Characteristics | | Subject Device CloudPoint FastDesign Chairside | Predicate device Abutment Design (K200100) | Comparison |
|---|---|---|---|---|
| Manufacturer | | Prismatik Dentalcraft, Inc. | 3Shape A/S | N/A |
| Product Code | | PNP | PNP | Same |
| Prescription Device | | Yes | Yes | Same |
| Intended Use | | Dental Abutment Design Software | Dental Abutment Design Software | Same |
| Indications for Use | | CloudPoint FastDesign Chairside is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae.<br><br>CloudPoint FastDesign Chairside is intended for use by a dental practitioner or dental laboratory staff for designing the patient-matched component of a two-piece hybrid dental implant abutment.<br><br>The resulting abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device. | Abutment Design is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae.<br><br>Abutment Design is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece, or hybrid dental implant abutment.<br><br>The resulting abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device. | Same except for the range of abutment designs the software supports. The subject device can design two-piece hybrid abutment; while the predicate device can design two-piece, one-piece, or hybrid abutment. The difference has no impact on the substantial equivalence determination. In addition, the minor differences in device trade names and the use of different terminology such as “patient-matched” v.s. “patient specific” do not affect the substantial equivalence determination. |
| Specifications/Features | Graphic UI | Yes | Yes | Substantially equivalent |
| | Windows OS platform | Yes | Yes | Substantially equivalent |

| Technological Characteristics | | Subject Device CloudPoint FastDesign Chairside | Predicate device Abutment Design (K200100) | Comparison |
|---|---|---|---|---|
| | Uses standard PC hardware | Yes | Yes | Substantially equivalent |
| | Digitally imports topography of teeth by 3D Scan | Yes. The software receives scan files containing topographical characteristics from an intraoral scanner in STL or PLY format. | Yes. The software receives scan files containing topographical characteristics from real teeth, dental impressions, or stone models in STL or DCM format. | Substantially equivalent. The only differences are that the subject device accepts scan files in STL or PLY format; while the predicate device accepts scan files in STL or DCM format. The difference has no impact on the substantial equivalence determination. |
| | Uses 3D CAD design tools | Yes | Yes | Same |
| | Patient specific abutment design | Yes. The software designs the patient specific component of a two-piece hybrid dental implant abutment. | Yes. The software designs the patient specific component of a two-piece, one-piece, or hybrid dental implant abutment. | Substantially equivalent. The only difference is that the subject device can design two-piece hybrid abutment; while the predicate device can design two-piece, one-piece, or hybrid abutment. The difference has no impact on the substantial equivalence determination. |
| | Implant Bar design | No | No | Same |
| | Export to remote milling machine by | Yes | Yes | Same |

| Technological Characteristics | | Subject Device CloudPoint FastDesign Chairside | Predicate device Abutment Design (K200100) | Comparison |
|---|---|---|---|---|
| | internet | | | |
| | Network Protocol | Internet/TCP-IP | Internet/TCP-IP | Substantially equivalent |
| | Intended users | Dental practitioners and dental technicians | Dental practitioners and dental technicians | Same |
| | Output type | Digital encrypted or non-encrypted proprietary or .STL/PLY file only of the patient specific abutment component. | Digital encrypted or non-encrypted proprietary or .STL file only of the patient specific abutment component. | Substantially equivalent. The only difference is that the subject device supports output file in STL or PLY format. The difference has no impact on the substantial equivalence determination. |
| | Device submission includes pre-manufactured prosthetics (endosseous dental implant abutments as per 21 CFR 872.3630) | No. The software relies on separate regulatory clearance for the abutment system. | No. The software relies on separate regulatory clearance for the abutment system. | Same |

PRISMATIK DENTALCRAFT, INC.

## DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The subject device, CloudPoint FastDesign Chairside, is substantially equivalent to the primary predicate device, Abutment Design (K200100), in intended use, indications for use and technological characteristics, including technical specifications/features and principles of operation.

The subject device, CloudPoint FastDesign Chairside, has the same intended use as the predicate device, Abutment Design (K200100), as a dental implant abutment design software and an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The subject device, CloudPoint FastDesign Chairside, has similar indications for use to the predicate device, Abutment Design (K200100). Both software devices are intended to be used by dental practitioners or dental laboratory staff for designing the patient-matched component of a dental implant abutment. The only difference in Indications for Use lies in that the subject device, CloudPoint FastDesign Chairside, is indicated for designing the patient specific component of a two-piece hybrid dental implant abutment; whereas the predicate device, Abutment Design (K200100), has a broader range of indications, which includes designing the patient specific component of a two-piece, one-piece, or hybrid dental implant abutment. The difference has no impact on the substantial equivalence determination.

The subject device, CloudPoint FastDesign Chairside, is substantially equivalent to the predicate device, Abutment Design (K200100), in terms of technical features. Both the subject device, CloudPoint FastDesign Chairside, and the predicate device, Abutment Design (K200100), accept scanned data of digital representations of a patient's dentition to design the patient-matched component of a dental implant abutment using 3D computer aided design tools with Graphic UI. The design outputs are then exported to a remote milling machine through internet connection with TCP/IP protocol. Both the subject device, CloudPoint FastDesign Chairside, and the predicate device, Abutment Design (K200100) are restricted to be used with 510(k) cleared abutment systems and design the endosseous dental implant abutment according to the requirements of the compatible abutment system or directions of a clinical professional. Both the subject device, CloudPoint FastDesign Chairside, and the predicate device, Abutment Design (K200100) receive imported scan data containing topographical characteristics of the patient's dentition and provide the user with the ability to create the matching abutment design using computer aided design.

The subject device, CloudPoint FastDesign Chairside, is substantially equivalent to the predicate device, Abutment Design (K200100), in terms of principle of operation. The fundamental principle of operation of the subject device, CloudPoint FastDesign Chairside, and the predicate device, Abutment Design (K200100), is the same. Both software devices use digital imaging tools for computer aided design (CAD) of dental implant abutments.

## VII. PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence include:

- Software verification and validation, according to the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", issued on May 11, 2005.
- Cybersecurity Analysis, according to the FDA Guidance Document “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”, issued on October 02, 2014

No clinical data is included in this submission.

Software Verification and Validation

The software design verification and validation were conducted by Prismatik Dentalcraft, Inc. to verify that the software development output met the input requirements, and to validate that the software specifications confirm to user needs and its intended uses, and that the requirements implemented through software can be consistently fulfilled. The results of the testing were used to address questions related to substantial equivalence based on differences in technical features between the subject device, CloudPoint FastDesign Chairside, and the predicate device, 3Shape A/S (K200100).

Software verification and validation testing was provided for the compatible abutment design library to demonstrate use with the subject device, CloudPoint FastDesign Chairside software suite. Software verification and validation testing was conducted to demonstrate that the restrictions prevent design of the patient-matched component of the two-piece hybrid dental abutment outside of the allowable design limitations, including screenshots under user verification testing. In addition, the software verification and validation testing established that the design limitations and specifications are locked and cannot be modified within the abutment design library.

Cybersecurity Analysis

Cybersecurity risk assessment, including hazard analysis, mitigation and design considerations pertaining to the intentional and unintentional cybersecurity risks, was performed for the subject device, CloudPoint FastDesign Chairside. Based on the risk assessment results, it was concluded that the benefits of the final device outweigh the residual risk after the risk control/mitigation, and that all risks were mitigated as far as possible.

## VIII. CONCLUSION

Based on the comparison on intended use, indication for use, technological characteristics, as well as non-clinical test data included in this submission, the subject device, CloudPoint FastDesign Chairside, has been shown to be substantially equivalent to the predicate device, Abutment Design (K200100).