January 15, 2020

Cendres+Metaux SA
Andrea Sparti
Regulatory Affairs Manager
Rue de Boujean 122
Biel/Bienne, 2501 SWITZERLAND

Re: K192251
Trade/Device Name: Livento© Press, Soprano 10©, Soprano©
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: September 27, 2019
Received: October 17, 2019

Dear Andrea Sparti:

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,

for Srinivas ‘Nandu’ Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192251

Device Name
Livento® press, Soprano® 10, Soprano®

Indications for Use *(Describe)*
The indications for use for Livento® press, Soprano® 10 and Soprano® are:
—Veneers
—Inlays and onlays
—Partial crowns
—Anterior and posterior tooth crowns
—Hybrid abutment crown
—3-pontic bridge in anterior tooth region
—3-pontic bridge in the premolar region up to max. 2nd premolar as a permanent abutment

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) Summary

510(k) number: K192251

Submitter
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Contact Person: Andrea Sparti
Date prepared: 15 January 2020

Device
Trade Name: Livento® press, Soprano® 10 and Soprano®
Common Name: Dental ceramic
Classification Name: Porcelain powder for clinical use
Regulatory Class: II
Product Code: EIH
Regulation Number: 21 CFR 872.6660

Primary Predicate Device
DCceram System
510(k) number: K141400

Device Description
The Livento/Soprano dental ceramic system comprise pressable ingots and compatible layering ceramic powders used in dental laboratories by the dental technician to create all ceramic restorations.
Livento® press is a pressable lithium disilicate glass-ceramic supplied in ingots of 3 grams. The material is supplied in different levels of translucency (MT, LT, ET, HO, Opal and Bleach) each in different dental shades of Vita A, B, C and D.
Soprano® 10 is a layering fluorapatite glass-ceramic supplied as powder suitable for veneering substructures made from Livento® press lithium disilicate glass-ceramic and zirconium oxide. It has a range of different translucency levels (Frame Modifier, Opaque Dentine, Dentine, Incisal/Enamel, Transparent, Clear) and is available in the Vita classic colors A, B, C and D as well as Bleach shades and Modifiers.
Soprano® shades, stains and glaze are glass ceramic dental porcelain material. They are intended to finish dental restorations and are offered in a variety of shades.

All Livento/Soprano dental ceramics meet the requirements of ISO 6872:2015.

Indication for Use

- Veneers
- Inlays and onlays
- Partial crowns
- Anterior and posterior tooth crowns
- Hybrid abutment crown
- 3-pontic bridge in anterior tooth region
- 3-pontic bridge in the premolar region up to max. 2nd premolar as a permanent abutment

Comparison of Technological Characteristics with the Primary Predicate Device

The legally marketed device to which CENDRES+METAUX SA is claiming equivalence is identified as DCceram System, K141400, manufactured by Ceramay GmbH & Co. KG. The DCceram System is comprised of pressable silica-based ceramic pellets and compatible layering porcelains powders used to create all-ceramic restorations.

Specifically, equivalence is claimed between the following products:

- DCceram Concept press & Livento® press
- DCceram 9.2 & Soprano® 10
- DCceram Concept Art stains, shades and glazes & Soprano® Flu-Stains, Flu-Shades and Glazes.

Substantial equivalence is based on indications for use, technological characteristics, material composition, and conformity with consensus standards.

The comparison of the candidate device to the predicate device shows that, when looking at comparable constituents, the devices have the same intended use:

- Manufacture of all-ceramic crowns and bridges by the press technique for DCceram Concept press and Livento® press
- Layering the pressed ceramic crown or bridge or a zirconium oxide framework for DCceram 9.2 and Soprano® 10
- Staining lithium disilicate glass ceramic or zirconium oxide in its final shades for ConceptArt and Soprano® Stains, shades and glazes

The indications are comparable, including veneers, inlays and onlays, partial and full crowns and 3-unit bridges in the anterior and premolar regions with the same limitations of including the second pre-molar as a terminal abutment.

The devices are made of the same materials:

- Silicate glass ceramic mainly composed of SiO_2, Al_2O_3, Li_2O, P_2O_5, K_2O, CaO, B_2O_3

The measured parameters according to ISO 6872 show slight differences between the subject device and the predicate. However, none are of clinical significance. Both devices conform to the consensus standard ISO 6872, which provides performance specifications satisfied by both the predicate and the candidate device.

Performance Data

This 510(k) submission includes the results of performance testing supporting compliance to International Standard ISO 6872:20015 as recognized by FDA. Measured parameters in a representative sample of the products included:

- Flexural strength,
- Chemical Solubility,
- Coefficient of Thermal Expansion,
- Glass Transition Temperature, and
- Radioactivity of ^{238}U.

The results show product compliance to the requirements of ISO 6872:2015.

The Livento/Soprano dental ceramics are surface contacting materials with contact with the oral mucosa with contact duration of more than 30 days (permanent contact). Biocompatibility evaluation was based on the similarity with the predicate device.

Conclusions

Based on the above, we conclude that Livento/Soprano dental ceramics are substantially equivalent to the predicate device DCceram System.