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

Schutz Dental Gmbh
Antje Maurer
International Sales Director
Dieselstrasse 5-6
Rosbach, DE 61191
GERMANY

October 24, 2016

Re: K151399
Trade/Device Name: Capo Hybrid, Capo Slow Flow, Capo Flow, Capo Natural, Capo Universal, Nano Paq, Nano Paq Flow
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Codes: EBF, EBC, EMA
Dated: May 22, 2015
Received: May 26, 2015

Dear Antje Maurer:

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" (21 CFR 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,

Susan Runner DDS, MA

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

510(k) Number (if known): K151399
Device Name: Capo Hybrid
Indications for Use:

Capo Hybrid is a light-curing hybrid composite containing an ultrafine, radiopaque glass filler and is indicated for placing fillings using adhesive techniques. It can be polished to a high lustre. Applications are:

- Direct anterior and posterior restorations in Black's class I, II, III, IV, and V cavities.
- Indirect restorations such as inlays, onlays and laminate veneers.
- Extended fissure sealing in molars and premolars.
- Endodontic posts
- Splinting mobile teeth.
- Adjusting the contours and shades to improve aesthetics.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K151399
Device Name: Capo Flow
Indications for Use:

Capo Flow is a light-curing, flowable, radiopaque, low viscosity composite. Applications are:

- Fissure sealing
- Extensive fissure sealing on molars and premolars
- Fillings in Black's class V cavities (cervical caries, eroded areas in roots, wedge-shaped defects)
- Minimally invasive fillings in Black's class I and II cavities in areas not exposed to severe occlusal loads
- Minimally invasive fillings in Black's class III cavities
- Restoring defects in enamel
- Blocking out undercuts
- Minimal adjustments to the contours and shade of the enamel

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known): K151399
Device Name: Capo Natural
Indications for Use:

Capo Natural is a light-curing composite containing an ultrafine, radiopaque glass filler and is indicated for placing fillings using adhesive techniques. Applications are:

- Direct anterior and posterior restorations in Black's class I, II, III, IV, and V cavities.
- Indirect restorations such as inlays, onlays and laminate veneers.
- Extended fissure sealing in molars and premolars.
- Endodontic posts.
- Splinting mobile teeth.
- Adjusting the contours and shades to improve aesthetics.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known): K151399
Device Name: Capo Slow Flow
Indications for Use:

Capo Slow Flow is a light-curing, flowable, highly radiopaque (210 % Al) composite with a high viscosity. Applications are:

- Fissure sealing
- Extensive fissure sealing on molars and premolars
- Fillings in Black's class V (cervical caries, root erosions, v-shaped lesions)
- Minimally invasive fillings in Black's classes I, II and III
- Corrections of enamel defects
- Blocking out undercuts
- Small corrections of shape and colour of the enamel

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known): K151399
Device Name: Capo Universal
Indications for Use:

Capo Universal is a light-curing composite containing an ultrafine, radiopaque glass filler and is indicated for placing fillings using adhesive techniques. Applications are:

- Direct anterior and posterior restorations in Black's class I, II, III, IV, and V cavities.
- Indirect restorations such as inlays, onlays and laminate veneers.
- Extended fissure sealing in molars and premolars.
- Endodontic posts.
- Splinting mobile teeth.
- Adjusting the contours and shades to improve aesthetics.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known): K151399
Device Name: NanoPaq Flow
Indications for Use:

NanoPaq Flow is a light-curing, flowable, radiopaque, low viscosity composite. Applications are:

- Fissure sealing
- Extensive fissure sealing on molars and premolars
- Fillings in Black's class V cavities (cervical caries, eroded areas in roots, wedge-shaped defects)
- Minimally invasive fillings in Black's class I and II cavities in areas not exposed to severe occlusal loads
- Minimally invasive fillings in Black's class III cavities
- Restoring defects in enamel
- Blocking out undercuts
- Minimal adjustments to the contours and shade of the enamel

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K151399
Device Name: NanoPaq
Indications for Use:

NanoPaq is a light-curing nano-composite for the adhesive filling technique. It contains an ultrafine, radiopaque glass filler. Applications are:

- Direct anterior and posterior tooth restorations in Black's classes I, II, III, IV, and V.
- Indirect restorations such as inlays, onlays and veneers.
- Extended fissure sealing on molars and premolars.
- Building up stumps.
- Splinting of loosened teeth.
- Corrections of shape and colour to enhance aesthetics.

Prescription Use __✓_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
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