MAR - 7 2012

510(k) Summary

CONTACT: Uri Yarovesky, President
Hilla Technologies Inc.
29229 Canwood St. #210
Agoura Hills, CA 91301
P. 818-991-5292
F. 818-991-5293
uriyarovesky@yahoo.com

DATE PREPARED: February 14, 2012

TRADE OR PROPRIETARY NAME: HILLA DIGITAL TRANSFERS

CLASSIFICATION NAME: DENTAL PORCELAIN

PREDICATE DEVICE: K000983

This summary includes only information that is also covered in the body of this 510(k) document, does not contain any puffery or unsubstantiated labeling claims, does not contain any raw data, i.e., contains only summary data, and does not contain any patient identification information. Confidential information is included.

DEVICE DESCRIPTION: HILLA DIGITAL TRANSFERS are ceramic stain powders in a decal form, for application to dental ceramic prosthetic devices. The decals are applied and fired on ceramic dental restorations. After firing the decal, what remains is a silicate ceramic stains, which are substantially equivalent to the silicate ceramic stains disclosed in K000983.

INTENDED USE: HILLA DIGITAL TRANSFERS are colored ceramic stains, supplied in a decal form, for firing onto dental ceramic prosthetic devices.

TECHNOLOGICAL CHARACTERISTICS vs. THE PREDICATE DEVICE: HILLA DIGITAL TRANSFERS are essentially identical to the predicate device, the stain powders of the Ceramix Porcelain System, K000983.

Both the HILLA DIGITAL TRANSFERS and Ceramix Porcelains System stains are applied to ceramic dental restorations to make the natural, esthetic, coloring effects at the incisal edges of such restorations. Both the HILLA DIGITAL TRANSFERS and Ceramix Porcelains System stains are fired to 850°C to burn off the organic components used to apply the HILLA DIGITAL TRANSFERS or the Ceramix Porcelains System stains.

HILLA DIGITAL TRANSFERS are a combination of colors of Ceramix dental stains in a decal form, which have an artistic and esthetic representation of the incisal details present in natural teeth, and eliminate the need for individual application of ceramic stain powders by a dental technician.

Both the HILLA DIGITAL TRANSFERS and the predicate Ceramix Porcelain System stains have the same technological characteristics, since the HILLA DIGITAL TRANSFERS contain primarily the Ceramix Porcelain stains. Both devices contain fine, colored glass (ceramic) powders that are fired in a dental laboratory oven to 850°C on dental ceramic restorations to create more esthetic dental ceramic restorations.

OTHER: We believe that the performance data provided herein support the safety and effectiveness of use of HILLA DIGITAL TRANSFERS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Hilla Technologies, Inc.
C/O Dr. Carolyn M. Primus
Primus Consulting
7046 Owl's Nest Terrace
Bradenton, Florida 34203

MAR - 7 2012

Re: K113575
Trade/Device Name: Hilla Digital Transfers
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: February 14, 2012
Received: February 22, 2012

Dear Dr. Primus:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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 yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113575

Device Name: HILLA DIGITAL TRANSFERS

Indications For Use: HILLA DIGITAL TRANSFERS are colored ceramic stains, supplied in a decal form, for firing onto dental ceramic prosthetic devices.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113575