DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 2006

Mr. Masimo Sasso
President
Dental Arte, Incorporated
12315 Oak Knoll Road, Suite 330
Poway, California 92064-5343

Re: K060086
Trade/Device Name: FENIIIIIIX
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: February 22, 2006
Received: February 22, 2006

Dear Mr. Sasso:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Chiu S. Lin, PhD
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): K060086

Device Name: *FENIIIIIIX*

Indications for Use: *FENIIIIIIX* system includes the following 6 sets of stains and dental porcelains:

FENIIIIIIX COLORATION KIT SN2000Y a porcelain stain system designed for easy application and natural fluorescent properties. This dental porcelain stain system can be used with most commercially available porcelain restorations, where porcelain's ability to mimic natural tooth appearance is important. The system provides optimum esthetics with the most consistently reliable results for the full range of shades.

The *FENIIIIIIX COLORATION KIT* stain system is ideal for high and low production laboratories and is available in 16 classic Vita® shades as well as Neutral Brown, Complex Gray, Blue Gray, Ochre; Rust and Red for matching bleached dentition with CTE Ranges of13.7 to 15.1. The full assortment is 22 Stains, 1 powdered glaze and 1 liquid glaze.

The stains in the SN2000Y kit fire at 900°C

FENIIIIIIX COLORATION KIT SN200Y is identical to the SN2000Y kit in function and content except that the stains in the SN2000Y kit fire at 750°C

FENIIIIIIX SUPER LIGHT WHITE KIT, a stain kit designed to produce perfectly white dental restorations. It includes one powdered stain and 1 liquid glaze

Prescription Use **X** and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Division of General Hospital
and Dental Devices
K060086

INDICATIONS FOR USE (Continued):

FENIIIIIIX SPEACIAL CLEAR KIT, This kit includes a series of whites designed to produce areas of whitish translucence and opalescence.

ASTARTE SUPER WHITE PORCELAIN KIT. This kit is specifically designed to create perfectly white dental restorations and can be used with most commercially available base and precious metal, dental alloys that are designed for porcelain fused to metal applications. It includes 1 powdered opaque, 1 powdered enamel, 1 powdered colorless glaze, 1 liquid opaque and 1 liquid dentine.

FENIIIIIIX ELIMINCRACK. This kit is used to repair cracks that form in porcelain dental restorations. It includes 1 powdered porcelain and 1 repair liquid.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...ion, General Hospital,
...Devices

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