3/8/99

SEP 29 1999

K984415

510(k) Summary

Company Name:

S.S. White Technology, Inc.
151 Old New Brunswick Road
Piscataway, NJ 08854

Company Contact, Regulatory Affairs:

Dave Taylor
S.S. White Technology, Inc.
151 Old New Brunswick Road
Piscataway, NJ 08854
Phone: (732) 752-8300 ext 390
Fax: (732) 752-0698
E-mail: dataylor@gateway.net

Device Name:

6500 Series Air Abrasion Systems

Predicate Devices:

KV-1, K#940776 (Kreativ, San Diego, CA), Mach Series, K#980216 (Kreativ, San Diego, CA), K#921748 (American Dental Technologies, Troy, MI), Microetcher, K#902836 (Danville Engineering) and the MicroPrep Cavity Preparation System, K#932997 (Sunrise Technologies, Inc.)

Device and Indications for Use:

The 6500-D, 6500-E, and 6500-F are pneumatic devices which combine pressurized air and abrasive powder (e.g. aluminum oxide or sodium bicarbonate) to produce a high velocity stream of particles to perform dental restorative procedures. The abrasive particulate is delivered via a small handpiece which is approximately the size of a dental drill handpiece. The systems are designed for ease of service and maintenance with a readily accessible refillable container for the particulate supply.

The 6500-D, 6500-E, and 6500-F are used for cavity preparation in Classes I, II, III, IV, and V. The uses include removal of tooth structure and restorative dental materials, and site preparation for pit and fissure sealant therapy and bonding of porcelain and ceramic. They are also used for restoration prophylaxis.

Discussion:

Since the intended use and technical specifications of the 6500-D, 6500-E, and 6500-F are virtually identical to the predicate devices, and the differences in the devices only serve to make them marketable, we believe the 6500 Series devices are substantially equivalent to the predicate devices and can be marketed under section 510(k) of the FD & C Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 1999

Mr. Dave Taylor
S.S. White Technologies, Incorporated
151 Old New Brunswick Road
Piscataway, New Jersey 08854-3761

Re: K984415
Trade Name: S.S. White Technologies, Models 6500-D, 6500-E, and 6500-F
Regulatory Class: III
Product Code: KOJ
Dated: November 26, 1998
Received: December 10, 1998

Dear Mr. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

510(k) submission: S.S. White Technologies 6500 Series Air Abrasion Devices

Indications for Use:

The S.S. White Technologies 6500 Series Air Abrasion Devices are used for cavity preparation in Classes I, II, III, IV, and V. The uses include removal of tooth structure and restorative dental materials, and site preparation for pit and fissure sealant therapy and bonding of porcelain and ceramic. They are also used for restoration prophylaxis.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984117

— PRESCRIPTION DEVICE