JUN 16 1998

510 (k) Summary

K980214

Regulatory Authority: Safe Medical Devices Act of 1990, CFR 807.87

Company Name:

Kreativ, Inc.
1517 Industrial Way SW
Albany, OR 97321

Company Contact, Regulatory Affairs

Jeff Lane
Kreativ, Inc.
1517 Industrial Way. SW
Albany, OR 97321
Phone: 541/924 2480

Device Name:

Mach 5, Mach 5 plus, Mach M, and Mach 6

Predicate Devices:

KV 1, K#940776 (Kreativ, Inc., Albany, OR), KCP 2000, K#921748 (American Dental Technologies, Troy, MI). and the MicroPrep Cavity Preparation System, K#932997, (Sunrise Technologies, Inc.).

Device and Indications for use:

The Mach 5, Mach 5 plus, Mach M, and Mach 6 are pneumatic devices which combine pressurized air and aluminum oxide powder to produce a high velocity stream of particles to perform dental restorative procedures, including preparation for pit and fissure sealant and composite restorations.

The units are capable of removing dental caries, old restoration materials, as well as healthy enamel and dentin to prepare the tooth surface for subsequent adhesion of restorative materials. The abrasive particulate is delivered via a small handpiece which is approximately the size of a high speed dental drill.

The systems are designed for ease of service and maintenance with readily accessed and refillable canisters for the particulate supply.

Discussion:

Since the intended use and technical specifications of the Mach 5, Mach 5 plus, Mach M, and the Mach 6 are virtually identical to the predicate devices, and the differences in the devices only make them easier to use and more adaptable to a variety of dental practice situations, we believe that the Mach 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

JUN 16 1998

Mr. Joe Forehand
Vice President of Operations
Kreativ, Incorporated
1517 Industrial Way S.W.
Albany, Oregon 97321

Re: K980216
Trade Name: Kreativ Mach 5, Mach 5 Plus, Mach M, and Mach 6
Regulatory Class: III
Product Code: KOJ
Dated: January 19, 1998
Received: January 21, 1998

Dear Mr. Forehand:

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

Exhibit 3a

Indications Statement

510(k) submission: Kreativ Mach Series Air Abrasion Systems: Mach 5, Mach 5+, Mach M, and Mach 6

Indications for use:

The Kreativ Mach Series Air Abrasion systems 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.

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K982116