

JUN 15 2000

510K Summary

X 990060

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

Company Name:

Kreativ, Inc.
9025 Balboa Ave.
San Diego, CA. 92123

Company Contact:

Joe Forehand
Kreativ, Inc.
9025 Balboa Ave.
San Diego, CA. 92123
(619) 514-4235

Device Name:

Mach 7

Predicate Devices:

KCP 2000	K921748	American Dental Technologies
MicroPrep	K932997	Sunrise Technologies
Mach 5	K980216	Kreativ, Inc.
Mach 6	K980216	Kreativ, Inc.

Device and indications for use:

The Mach 7 is an air abrasion pneumatic device which combines pressurized air and aluminum oxide powder to product a high velocity stream of particles to perform dental restorative procedures, including preparation for pit and fissure sealant and composite restorations.

The unit is capable of removing dental caries, old restorative 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 hand piece which is approximately the size of a high speed dental drill.

The system is 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 7 are virtually identical to the predicate devices and the differences in the device only make it easier to use, more reliable and more adaptable to a variety of dental practice situations, we believe that the Mach 7 is 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

JUL 5 2000

Mr. Joseph M. Forehand
Vice President and General Manager
Kreativ, Incorporated
9025 Balboa Avenue
San Diego, California 92123-1509

Re: K990060
Trade Name: Mach 7
Regulatory Class: II
Product Code: KOJ
Dated: January 8, 1999
Received: January 8, 1999

Dear Mr. Forehand:

This letter corrects our substantially equivalent letter of June 15, 2000, regarding the Regulatory Class.

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 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). 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 (Pre-market 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug

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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" (21CFR 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/dsma/dsmamain.html>".

Sincerely,

Susan Renney
for

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) Number:

Device Name: Mach 7

Indication for Use:

The Kreativ Mach 7 Air Abrasion system is 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. It may also be used for restoration prophylaxis.

(Please do not write below this line—continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over the Counter Use
(Per 21 CFR 801.109)

Optional Format 1-2-96

Shirley W. Stephens MSR
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number 1K990060