

K955050

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MAR -7 1996

**Appendix V
Summary of Safety
and Effectiveness Information**

**Section 510(k)
Premarket Notification**

Summary of Safety and Effectiveness Information

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name:

Dove Systems, Inc.
4280 Higuera Road
San Jose, CA 94328
(408) 223-2418

**Company Contact
Regulatory Affairs:**

Arthur Vassiliadis, Ph.D.
Dove Systems, Inc.
4280 Higuera Road
San Jose, CA 94328
(408) 223-2418

Device Name:

Jetstream Cavity Preparation System.

Predicate Devices:

KCP 2000 Cavity Preparation System (American Dental Laser, Troy, Michigan) Microprep Cavity Preparation System (Sunrise Technologies, Inc.) Kv-1 Cavity Preparation System (Kreativ, Inc.)

Device Description:

The Jetstream System is a pneumatic device which combines 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 Jetstream is capable of removing dental caries, old composite 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 Jetstream consists of a console, handpiece, and a footswitch. Specifications for the Jetstream System are provided in the table below. The console houses the system pneumatics, simple, easy to use controls, and canisters for holding the particulate supply. The system is designed for easy service and maintenance with easily accessed and refillable canisters for the particulate supply.

Comparison With Predicate Device:

FEATURE	Jetstream	Microprep	Kv-1	KCP 2000	SE?
Cutting material	Aluminum Oxide Powder 50µ particles	Aluminum Oxide Powder 50µ particles	Aluminum Oxide Powder 27µ & 50µ particles	Aluminum Oxide Powder 27µ & 50µ particles	Yes
Velocity settings	Continuously Variable 40-120 psi	Continuously Variable 80-120 psi	Continuously Variable 40-120 psi	Slow, Medium, High (40-120-140) psi	Yes
Delivery medium	Compressed Air - Wall source	Compressed Air - Internal Compressor	Compressed Air - Wall source	Compressed Air - Wall source	Yes
Operating modes	Pulse & Continuous	Pulse & Continuous	Pulse & Continuous	Continuous Only	Yes
Evacuation	Other Evacuator	Proprietary - "Quickevac"	Other Evacuator	Built In	Yes
Electrical	100-240V, 50/60 Hz	110-220-240V 50/60 Hz	100-240V, 50/60 Hz	110V	Yes
Controls	Touch Pad Membrane Switches	Yes			
Delivery system	Handpieces	Handpieces	Handpieces	Handpieces	Yes
Indications	Cavity Preparation Removal of decayed and sound tooth structure Removal of restoration materials Prep for pit and fissure sealant Modification of enamel and dentin for increased bond strength	Cavity Preparation Removal of decayed and sound tooth structure Removal of restoration materials Prep for pit and fissure sealant Modification of enamel and dentin for increased bond strength	Cavity Preparation Removal of decayed and sound tooth structure Removal of restoration materials Prep for pit and fissure sealant Modification of enamel and dentin for increased bond strength	Cavity Preparation Removal of decayed and sound tooth structure Removal of restoration materials Prep for pit and fissure sealant Modification of enamel and dentin for increased bond strength	Yes
K-Number	Pending	K932997	K940776	K921748	Yes

Summary of Adverse Product Experience:

As of September 1995, Dove Systems, Inc. conducted a database search of the published literature to identify adverse use experience with cavity preparation systems. This literature review revealed the following adverse event experience with cavity preparation systems.

1. Cutting of adjacent soft tissue.
2. Subcutaneous injection of air and/or air and abrasive particles.
3. Etching of adjacent tooth surface.
4. Reduced effect on existing gold or amalgam restorations
5. Infection

Additional Information

A bibliography of selected articles is available from Dove Systems, Inc. upon request.

Conclusions:

Based on the comparison of the technical specifications of the Jetstream Cavity Preparation System with the KCP 2000 Kinetic Cavity Preparation System, the Microprep Cavity Preparation System, and with the Kv-1 Cavity Preparation System, the company concludes that the Jetstream Cavity Preparation System is substantially equivalent. Dove Systems, Inc. believes that the the Jetstream Cavity Preparation System may reasonably be expected to be safe and effective when used according to its labeling by properly trained individuals. The adverse events identified with the use of the Jetstream are the same or similar to the adverse events associated with the use of the referenced equivalent devices.