

K970484

510(k) SUMMARY

As Required by the Safe Medical Devices Act of 1990

IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICE

PREDICATE DEVICE

MICROETCHER™

MICROETCHER is a compressed air driven dental sandblasting device intended for intra-oral use to roughen dental hard tissues or restorative materials to enhance bonding of resin materials. The device is a hand held instrument resembling a dental handpiece in shape and function. The unit is operated at 60-100 psig of compressed air. A venturi principle forces an abrasive, aluminum oxide (50µm particle size), toward the object to be abraded. The high velocity abrasive imparts sufficient energy to abrade and remove material.

The device can be used extra-orally for similar purposes, that is, to roughen dental restorations to enhance bonding or to behave as a cleaning device.

DESCRIPTION OF APPLICANT DEVICE

ACCU-PREP™

ACCU-PREP is virtually identical to the MICROETCHER in design and function. The two models of the device, Type I and Type II are identical in design and function but differ cosmetically. That is Type I is nearly identical to the MICROETCHER and Type II is esthetically more pleasing. In addition, Type II has the abrasive reservoir in the center of the handpiece as opposed to the back end as in the MICROETCHER and it is completely autoclavable. The ACCU-PREP operates at somewhat lower minimum pressure than the MICROETCHER, 40 psig as opposed to 60.

INTENDED USES OF APPLICANT DEVICE

ACCU-PREP is intended to be used to abrade and enhance the bond between the prepared tooth and cast dental metals for Maryland bridges, for cementation of cast metal restorations, for porcelain repair, as a porcelain etch substitute, to prepare indirect composite restorations for cementation, for repair of composite or resin restorations, repair of acrylic facings on cast restorations, endodontic post preparation, denture repairs, and orthodontic applications such as: preparation of brackets to enhance bonding, cement removal from brackets, and enhancement of adhesion to tooth structure.

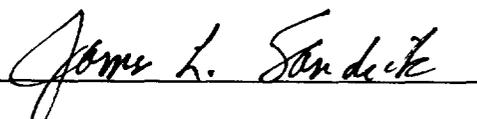
SCIENTIFIC CONCEPTS and SIGNIFICANT PERFORMANCE CHARACTERISTICS

The scientific concepts of this device are basic. A relatively high velocity stream of compressed gas (air), when blown across the opening of a tube set at 90 degrees to the air stream creates a low pressure at the opposite end of the perpendicular tube. This low pressure (vacuum) sucks up an abrasive powder from a reservoir and propels the abrasive thereby abrading the surface of an object in its path. The phenomenon is analogous to a perfume bottle. The abrasive powder behaves as the perfume, that is, as air is blown across the opening the abrasive powder is blown into the air stream.

Comparison of ACCU-PREP to the predicate device shows both are very similar with the major difference being esthetics. The proposed new products, Types I and II, are functionally identical to the predicate device but are more esthetically acceptable to the patient as well as to the dentistry and dental auxiliary. One notable difference between the two is the applicant device operates at lower air pressure.

Both employ 50 μm aluminum oxide as the primary abrasive but other grits can be used where appropriate. The range of normal grit sizes is 0.05 to 90 μm

Since both devices appear essentially identical their performances were compared by testing in actual use situations. Shear bond tests were performed on human extracted teeth using identical conditions with the only difference being the device abrading the substrate. No statistically significant difference was found in this test at $p \geq 0.05$. Examination of abraded surfaces using Scanning Electron Microscopy showed virtually identical results.



James L. Sandrik, Ph.D.
BISCO, Inc.
Itasca, IL 60143

February 7, 1997



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. James L. Sandrik, Ph.D.
Director of Technical Affairs
Bisco, Incorporated
1500 West Thorndale Avenue
Itasca, Illinois 60143

JUL 1 1997

Re: K970484
Trade Name: Accu-Prep
Regulatory Class: III
Product Code: KOJ
Dated: February 7, 1997
Received: February 10, 1997

Dear Dr. Sandrik:

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.

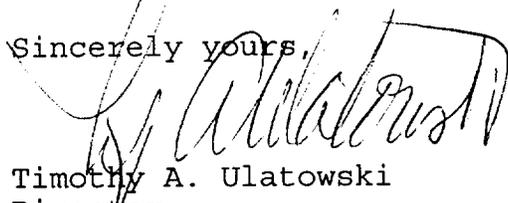
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the 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 pre-market 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.

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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) 594-4618. 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 at (301) 443-6597.

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 for USE

510(k) Number (if known): --

Device Name: ACCU-PREP

Indications for Use:

1. Maryland Bridges (resin bonded bridges): for preparation of cast metal framework of both non-precious (Ni-Cr) and noble (Au, Pt, Pd) alloys.
2. Cast restoration cementation: for preparation of intaglio surface of cast metal restorations to enhance micromechanical bonding especially of traditional cements (zinc phosphate).
3. Porcelain repair: for preparation of exposed metal (and porcelain) to repair failed porcelain fused to metal restoration intra-orally.
4. Porcelain etch substitute: for preparation of intaglio surface of porcelain restorations in place of etching with hydrofluoric acid in the mouth.
5. Composite surface preparation substitute: for preparation of intaglio surface of composite or polymeric restoration in place of surface active agents (i.e. methyl methacrylate).
6. Composite/polymeric restoration repair: for preparation of exposed failed restoration as in 5 above.
7. Repair of acrylic facings on cast restorations: for preparation of cast metal surface to enhance bond of self-cure acrylic facing to restoration.
8. Endodontic post preparation: for preparation of endo post to enhance micromechanical bond of post to prepared tooth.
9. Denture repairs: for preparation of denture base to facilitate repairs.
10. Orthodontic applications: for preparation of ortho brackets to enhance bonding to the bracket. For cement removal from brackets before re-bonding. For enhancement of adhesive to tooth structure.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRL, Office of Device Evaluation (ODE)

(Division Sign-Off) *Suzanne Bunker*
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K97048U

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)