

K 981869

I. SUMMARY OF SAFETY AND EFFECTIVENESS

1. Name and Address

This Summary of Safety and Effectiveness is being submitted by Professional Dental Manufacturing, Inc., 633 Lawrence Street, Batesville, Arkansas 72501. The telephone number is 870-698-2300.

2. Name of the Device

The device is generally known as a dental prophylaxis angle.

3. Identification of Predicate Device(s)

Dentsply's NUPRO® Disposable Prophy Angle.

4. Description of the Device

The device is a disposable dental prophylaxis angle which consists of a plastic body integrally formed with a drive mechanism, and a rubber cup that attaches to a retention knob or stud on the angle. The prophy angle has a slot for connecting the angle to a dental handpiece, which powers the prophy angle. The drive shaft of the prophy angle allows the rubber prophy cup to rotate.

5. Intended Use of the Device

Professional Dental Manufacturing, Inc.'s Pro-Flex™ Disposable Prophy Angle is intended for one time use by dental professionals during general prophylaxis. Pro-Flex™ is used to clean and polish teeth by application of a prophy angle with a rotating rubber cup, combined with a cleaning and polishing paste or powder, to the surfaces of teeth.

6. Comparison of Technological Characteristics

The differences in design between the Pro-Flex™ and the predicate device are very minor and do not impact the safety and effectiveness of the device in any significant way since the function and intended use are the same.

7. Safety

Professional Dental Manufacturing, Inc. reviewed the Medical Device Records (MDR) filed with CDRH during the period from 1992 through 1996 for information on prophy angles which may have caused a death or serious injury. Of the more than 200 MDRs filed, no serious injury events were reported. A single MDR indicated that a disposable prophy angle purportedly caused grooves or wearing away of enamel on the facial aspects of several teeth.

The other events reported were malfunctions falling into one of the following categories: the prophy angle stalled or locked up, the drive gears came apart, or the angle got hot. Several events reported that the rubber cup came off the prophy angle, occasionally in the patient's mouth, but no injuries were reported due to this or the other described malfunctions.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 1998

Bob Zahradnik, Ph.D.
Professional Dental Manufacturing, Inc.
633 Lawrence Street
Batesville, Arizona 72501

Re: K981869
Trade Name: Pro-Flex™ Disposable Prophylaxis Angle
Regulatory Class: I
Product Code: EFB
Dated: May 28, 1998
Received: May 28, 1998

Dear Dr. Zahradnik:

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 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

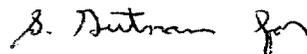
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 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

510(k) Number (if known): _____

Device Name: Pro-Flex™ Disposable Prophy Angle

Indications For Use: For one time use as part of a professionally administered prophylaxis treatment, to clean and polish teeth.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Rosner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K981569

Prescription Use

OR

Over-the-Counter Use _____