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PALISADES PHARMACEUTICALS, INC.

PALISADES DENTAL, Division of Palisades Pharmaceuticals, Inc.

P.O. BOX 579 • 64 NORTH SUMMIT STREET • TENAFLY, NEW JERSEY 07670 • (201) 569-8502 • 1-(800) 237-9083 • FAX (201) 569-7416**510(K) SUMMARY**I. **Submitter:**

Palisades Dental
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II. **Date 510(k) Summary Prepared:** August 1, 1996III. **Trade Name:** Impact Air 45 HandpieceIV. **Classification Name:** Dental Handpiece (21 C.F.R. §872.4200)V. **Predicate Devices:** Midwest Quiet Air Handpiece

VI. **Device Description:** The Impact Air 45 Handpiece is an air-powered dental handpiece. The handpiece has an angled head shank with a back angle of 45 degrees. It is intended for use with all friction-grip bur that conform to I.S.O. and A.D.A. recommended operating air pressure is between 32 and 40 pounds per square inch ("psi"), which results in high-speed bur rotation (approximately 400,000 to 500,000 revolutions per minute ("rpm")). The device includes a water line that directs water onto the spinning bur, which forms a cooling mist and also helps irrigate the working area. One model of the device also includes a fiberoptic bundle that directs light onto the working area.

The device may be connected to a standard compressed air source found in virtually all dental units. The use of filtered air is recommended. The air supply enters the device through a tube in the handle and turns the turbine, which is in the head of the device, thus spinning the bur.

The Impact air 45 can be sterilized by autoclave when processed for 35 minutes at 250 degrees. Data indicate that after 250 sterilization cycles the handpiece continues to function appropriately.

- VII. Substantial Equivalence: The Impact Air as compared with the predicate device has the same intended use, does not raise different questions of safety and effectiveness, and is fundamentally the same in operating principle, design, materials, energy source, and other characteristics. Like the predicate device, the Impact air 45 has principally stainless steel construction; is air-powered, with a high-speed turbine in the head of the device; attaches to a standard connection for compressed air found in most dental units; and is slim, lightweight and easy to manipulate.