K964590

C. EXECUTIVE SUMMARY

APR 22 1997

1. Reason for Submission

Premarket notification, as required under Section 510(k) of the Federal Food, Drug, and Cosmetic (FD&C) Act, facilitates the marketing of medical devices that are "new" to a company but substantially equivalent to devices that are already legally marketed. This submission provides the premarket notification required by section 510(k) of the Act and 21 CFR §807.87.

2. Description

The device for which 510(k) recognition of substantial equivalence is sought is an ultrasonic scaler intended for use during dental and periodontal therapy treatments to remove calculus deposits from teeth by application of an ultrasonic vibrating scaler tip to the teeth.

3. Substantial Equivalence

Comparison in terms of "substantial equivalence" is made to other marketed devices. Professional Dental Manufacturing, Inc.'s device is substantially equivalent to predicate devices because it has the same intended use as a host of ultrasonic scalers, in particular, Dentsply's Cavitron® Ultrasonic 3000, 1010 and 660 Scalers, Johnson & Johnson's Alfa-Sonic Hygienic Scaler Model 300 and Healthco's Air Flow II Scaler. For purposes of this PMN, we will compare the Pro-Select3™ to the Cavitron® Model 3000.

This PMN establishes that the Pro-Select3™ is substantially equivalent to the predicate device in its respective ability to remove calculus deposits from the teeth. Furthermore, this PMN establishes that Pro-Select3™'s technological characteristics are similar enough to the Cavitron® devices that it will not affect safety and effectiveness.