

K961158

MAY 23 1996

9. SMDA Summary of Safety and Effectiveness - "510(k) Summary"

A. Submitter Information

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Date Prepared: March 20, 1996

B. Device Identification

Common/Usual Name	Piezoelectric Ultrasonic Scaling Generator
Proprietary Name:	SUPRASSON P5 Booster

C. Identification of Predicate Device(s)

The SUPRASSON P5 Booster is substantially equivalent to its predicate device, SUPRASSON P-MAX (K942139), previously cleared and currently marketed.

D. Device Description

The SUPRASSON P5 Booster ultrasonic scaler consists of three primary components: the scaling instrument (PAM) "handpiece", the control panel case, and the footswitch.

The scaling instrument (PAM) "handpiece" is held in the physician's hand, but can also be stored in the holder located onto the case. The handpiece is connected to the control panel case via a fixed electrical cable connection. Tips are mounted by means of a tip wrench at the extremity of the handpiece. All SUPPRASSON P5 Booster tips vibrate in a single plane (vibration from front to rear and along the tip axis) via piezoelectric ultrasonic power. This rectilinear motion provides a more accurate and more comfortable approach to the tooth and gum. The enamel and cement are protected from unnecessary lateral impacts.

The SUPRASSON P5 Booster, similar to its predicate device, SUPRASSON P-MAX (K942139), operates from the action of cavitation, following the propagation of ultrasounds in a frequency spectrum comprised between 27 and 33 kHz and a mechanical effect following vibration of the tips mixing with water within a range of maximum amplitudes varying from 20 to 310 μm .

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The portable plastic control panel case includes all control and ultrasonic power generation functions. A visible light diode informs the user when the device is in enable mode; it also serves as an indicator for the power regulation potentiometer knob. The power settings can be varied from 1-14, dependent upon the clinical application.

Housed in the portable case, internal electronics generate electrical signals at the ultrasound frequency in order for the tip screwed at the extremity of the handpiece to vibrate. Irrigation is provided by a water line manually controlled by tap knob which adjusts the spray at the tip of the handpiece, and is located on the flat side of the control panel case.

Connections to the case are all shorter than 3 m:

- the AC mains cable, 3 conductors, fixed, unshielded;
- the PAM cable, 3 conductors, fixed, unshielded;
- the footswitch cable, 2 conductors, fixed, unshielded.

The footswitch pedal has two functions. Pressure on the pedal activates/deactivates piezoelectric ultrasonic power triggering, and enables/disables the flowswitch, located inside the control panel case, for irrigation.

E. Substantial Equivalence

The technical characteristics are almost identical to those of the Satelec SUPRASSON P-Max. Refer to Table A for a comparison with the predicate device. Differences that exist between these devices relating to technical specifications, materials, physical appearance, and control systems do not affect the relative safety or effectiveness of the SUPRASSON P5 Booster relative to its predicate.

The SUPRASSON P-Max and SUPRASSON P5 are intended to provide overall prophylaxis and preservation of soft and hard tissue during the 3 standard dental treatments; Scaling, Periodontics, and Endodontics.