

K960889

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XIII. 510(k) SUMMARY [807.92(c)]

**Applicant name:**

San Diego Swiss Machining  
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**DEVICE NAME**

Trade Name: *Sapphire Plus® Tips*  
Common Name: Ultrasonic files  
Classification Name: Ultrasonic Scaler, Accessories

**THE PRODUCT AND ITS INTENDED USE**

The San Diego Swiss Machining *Sapphire Plus® Tips* are utilized in reconstructive dental procedures (crown preparation), periodontic preparative procedures, tissue scaling, plaque/bone removal, endodontic retreatment and root preparation.

The devices are used during dental cleaning and periodontal (gum) therapy to remove calculus deposits from teeth by application of ultrasonic vibration and in various endodontic applications to prepare the tooth and/or root of the tooth for repair.

Four different types of tips will be manufactured by San Diego Swiss Machining as follows:

Scaler Tips  
Plugger Tips  
Cutting Tips  
Spreader Tips

The tips have been designed with an assortment of bends and/or angles to allow greater flexibility during debridement, cleansing, irrigation, disinfection, canal shaping and other various endodontic applications. The tips will be made of 13-8 stainless steel and coated with titanium nitride and/or zirconium nitride materials.

**STATEMENT OF SUBSTANTIAL EQUIVALENCE**

The San Diego Swiss Machining considers the *Sapphire Plus® Tips* to be substantially equivalent to FDA-cleared, as depicted in Table #1.

**TABLE #1 --SUMMARY OF SUBSTANTIAL EQUIVALENCY**

	<b>San Diego Swiss Machining</b>	<b>EMS</b>	<b>Spartan USA</b>	<b>EIE</b>	<b>Amadent</b>	<b>Dentsply Cavitron</b>
<b>Device Name</b>	Sapphire(R) Plus Tips	Piezon Master 400 Ultrasonic Tips	Piezo-Electric Scalers Models J-3 and S-3	Ultrasonic Tips	Neosonics-D	Endosonic Files
<b>Composition</b>	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
<b>Intended Use</b>	Reconstructive dental procedures, crown prep, periodontic prep. proc., tissue scaling, root prep.	Reconstructive dental procedures (crown prep.), periodontic prep. proc., tissue scaling, root prep.	Reconstructive dental procedures (crown prep.), periodontic prep. proc., tissue scaling, root prep.	Endodontic root prep	Tooth and sub- gingival scaling and root planing	Canal debridement, cleansing, canal shaping
<b>Operational Principles</b>	Ultrasonic Energy	Ultrasonic Energy	Ultrasonic Energy	Ultrasonic Energy	Ultrasonic Energy	Ultrasonic Energy
<b>Coating(s)</b>	Titanium Nitride Zirconium Nitride	None	None	None	Diamond (Tips)	None

**Performance Data:** N/A

**Nonclinical Data:** N/A

**Clinical Data:** N/A

-- END OF 510(k) SUMMARY -