K962544 SEP 20 1996

510(k) Summary

DSP Worldwide Snowden-Pencer Micro Diamond-Point™ Dissection Needles

(per 21 CFR 807.92)

1. Date of Preparation: September 12, 1996

2. Sponsor/Applicant : DSP Worldwide
Snowden-Pencer
5175 South Royal Atlanta Drive
Tucker, GA 30084

DSP Worldwide
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Fall River, MA 02720-4740

3. Contact Name: Mr. Timothy N. Thomas
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DSP Worldwide
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4. Device Name:

Trade/Proprietary Name:	Micro Diamond-Point™ Dissection Needles
Common/Usual Name:	Electrosurgical electrode
Classification Name:	Accessory to electrosurgical cutting and coagulation device

5. Identification of the predicate or legally marketed device(s) to which equivalence is being claimed:

Colorado MicroDissection Needle (K881763)

6. Device Description:

The DSP Worldwide Snowden-Pencer Micro Diamond-Point™ Dissection Needles are inserted into the electrosurgical handpiece. As with all other electrosurgical electrodes, energy is applied to the tissue with the highest concentration at the tip of the electrode. The Micro Diamond-Point™ Dissection Needles are provided in a variety of lengths and configurations. The electrode consists of a tungsten needle tip inserted into a stainless steel sleeve. This needle assembly is then covered with two layers of heat shrink tubing for insulation. Micro Diamond-Point™ Dissection Needless are provided nonsterile, for single use only. Devices are provided three per package and require sterilization prior to use. Sterilization instructions are provided in device labeling.

7. Intended Use:

The DSP Worldwide Snowden-Pencer Micro Diamond-Point™ Dissection Needles are electrosurgical electrodes which are intended for use as accessories to electrosurgical devices to cut tissue (dissection) and control bleeding for general, plastic, and reconstructive surgery.

8. Comparison of Technological Characteristics:

The DSP Worldwide Snowden-Pencer Micro Diamond-Point™ Dissection Needles are equivalent the Colorado MicroDissection Needles in design, materials, operational characteristics, and sterility. Any difference between devices is minor and raises no new issues of safety and effectiveness.