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510(k) Summary  
DSP Worldwide Snowden-Pencer Dermatome Blade  
(per 21 CFR 807.92)

1. Date of Preparation

June 18, 1996

2. Sponsor/Applicant

DSP Worldwide  
Snowden-Pencer  
5175 South Royal Atlanta Drive  
Tucker, GA 30084

DSP Worldwide  
600 Airport Road  
Fall River, MA 02720-4740

3. Contact Name

Timothy N. Thomas, Vice President, Regulatory Affairs and Quality Assurance  
DSP Worldwide  
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4. Device Name

Trade/Proprietary Name: Dermatome blade  
Common/Usual Name: Padgett dermatome blade  
Classification Name: Accessory to Padgett Dermatome

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

Padgett Dermatome Blades

6. Device Description

The DSP Worldwide Snowden-Pencer Dermatome Blade is secured to the Padgett Dermatome head using the securing nut. The blade oscillates on the horizontal plane to harvest a split thickness of skin from a donor site for grafting. It is provided in one size only and consists of the stainless steel used for many surgical applications. Blades are provided sterile, single use, and disposable in individual Tyvek and polypropylene pouches. Devices are sterilized using gamma sterilization.

7. Intended Use

The DSP Worldwide Snowden-Pencer Dermatome Blade is intended for use as an accessory to Padgett type dermatomes.

8. Comparison of Technological Characteristics

The DSP Worldwide Snowden-Pencer Dermatome Blade is equivalent to other currently marketed Padgett type dermatome blades in design, materials, operational characteristics, and sterility. Any difference between devices is minor and raises no new issues of safety and effectiveness.