

**510(k) Summary of Safety and Effectiveness**

**K964258**

JAN 16 1997

<b>Submitter:</b>		<b>Date of Preparation:</b> October 21, 1996	
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Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			
<b>Product Information:</b>			
Trade name: Instruments for Endoscopic Subfascial Discision of Perforating Veins (ESDP)		Model number: 8781	
Common name: Operating Tubes Operating Telescope Laser Guide Knife		Classification name: Endoscopic Accessories	
<b>Information on devices to which substantial equivalence is claimed:</b>			
510(k) Number	Trade or proprietary or model name	Manufacturer	
1	1 see Contents of submission	1	
2	2	2	
3	3	3	
4	4	4	
5	5	5	
6	6	6	

**1.0 Description**

The device consists of an operating telescope, endoscopic operating tube, a laser guide, and a hook knife.

**2.0 Intended Use**

The "ESDP" instrument set is used for minimally invasive visualization and diagnostic and therapeutic procedures of superficial veins in the lower extremities, e.g. the saphenous vein. The intervention takes place under sterile conditions.

**3.0 Technological Characteristics**

There are no significant technological characteristics of the new device compared to the existing device.

**4.0 Substantial Equivalence**

The ESDP systems substantially equivalent to devices sold or previously sold by Richard Wolf Medical Instruments. Specifically models 8981.01, 8449.20, 8960.01/02/03, 4937D, 8383.753, and 8267.10.

**5.0 Performance Data**

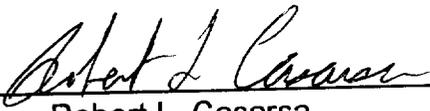
No data generated.

**6.0 Clinical Tests**

No clinical tests performed.

**7.0 Data Conclusions**

No data available.

By:   
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