

NOV 26 1996

1K963757

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

<b>Submitted by:</b>		<b>Date of Preparation:</b> September 13, 1996	
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<b>Contact name:</b> Mr. Robert L. Casarsa			
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<b>Product Information:</b>			
<b>Trade name:</b> Irrigation/Suction Handle with sheath		<b>Model number:</b> Handle - 8475.221. Sheath - 8475.032	
<b>Common name:</b> Sinus irrigator / suction device		<b>Classification name:</b> irrigator. sinus	
<b>Information on devices to which substantial equivalence is claimed:</b>			
<b>510(k) Number</b>	<b>Trade or proprietary or model name</b>	<b>Manufacturer</b>	
1 pre enact.	1 Suction / irrigation handle 8475.25	1 Richard Wolf M.I.C.	
2	2 Suction / irrigation handle 8475.26	2 Richard Wolf M.I.C.	
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**1.0 Description**

The irrigation / suction handle with sheath allows the insertion of a 4.0mm telescope and provides the physician the ability to view, apply irrigation fluids, and suction the cavity.

## 2.0 Intended Use

The Sinus Irrigation / Suction Handle and the accompanying sheath are used to provide a means for irrigation fluids to be introduced into the sinus cavity, a means of suction from the same cavity and a holder for a 4.0mm telescope to view the sinus cavity.

The Sinus Irrigation / Suction Handle can be used in conjunction with laser procedures and may be used with warm (heated) irrigation solutions. One such procedure is the VideoHydrascopic technique developed by Daniel Schuman, MD.

## 3.0 Technological Characteristics

There are no new technological characteristics for the irrigation / suction handle.

## 4.0 Substantial Equivalence

The irrigation / suction handle is substantially equivalent to prior suction / irrigation handle sold by Richard Wolf Medical Instruments Corporation. The predicate devices are listed in the information box above.

## 5.0 Performance Data

No performance data was obtained.

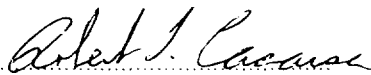
## 6.0 Clinical Tests

No clinical tests were performed.

## 7.0 Conclusions Drawn

The irrigation / suction handle is substantially equivalent to products currently marketed, particularly devices sold by Richard Wolf.

By:



Robert L. Casarsa  
Quality Assurance Manager

Date:

