

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

<b>Submitter:</b>		<b>Date of Preparation:</b> October 15, 1996	
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<b>Product Information:</b>			
<b>Trade name:</b> Hystero CO <sub>2</sub> -Pneu		<b>Model number:</b> 2221	
<b>Common name:</b> Insufflator, Hysteroscopic		<b>Classification name:</b> Insufflator, Hysteroscopic	
<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 Hysteroscopy-Insufflator 2020	1 Richard Wolf M.I.C.	
2 K880314	2 Hysteroscope Autonom 4992	2 Richard Wolf M.I.C.	
3 K924523	3 HYS - Surgiflator	3 WOM GmbH, Germany	
4	4 Hamou-Micro-Hysteroflator	4 Karl Storz	
5	5 Hystero-Insufflator Electronic	5 WISAP	
6	6	6	

**1.0 Description**

They Hystero-CO<sub>2</sub>-Pneu 2221 supplies CO<sub>2</sub> gas from cylinders or central gas supplies to dilate the cavum uteri by the CO<sub>2</sub> gas insufflation.

The gas pressure and flow rate are controlled according to the instructions by the device user.

**2.0 Intended Use**

The Hystero CO<sub>2</sub>-Pneu is designed for dilating the cavum uteri with CO<sub>2</sub> gas during diagnostic and operative hysteroscopy.

**3.0 Technological Characteristics**

The pressure and flow values are checked by microprocessor control. A number of independent safety devices guarantee safe and problem-free insufflation.

The intra-uterine pressure can be steplessly preselected between 10 mmHg and 100 mmHg and reduced in steps (1 mmHg) to 0 mmHg or increased to 150 mmHg. The flow rate can also be preselected between 10 ml/min and 99 ml/min and reduced in steps (1 ml/min) to 0 ml/min.

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These values can be displayed on-screen in order to document the pressure, flow, and gas consumption values during intervention via video equipment. Additionally user defined text can be displayed on-screen by means of a separate keyboard.

All relevant measuring data can be transmitted to a printer by a serial interface.

#### 4.0 Substantial Equivalence

The Hystero CO<sub>2</sub>-Pneu 2221 is substantially equivalent to pre-enactment devices and 510(k) devices sold by Richard Wolf and to various existing hysteroscopic insufflators on the market. The differences do not affect safety or effectiveness of the device.

#### 5.0 Performance Data

Bench data illustrating the intrauterine pressure at various output pressures and flow rates show that the preselected values are in accordance to the measured values within the specified deviations.

#### 6.0 Clinical Tests

No clinical tests performed.

#### 7.0 Data Conclusions

Hystero CO<sub>2</sub>-Pneu 2221 is designed and tested to guarantee the safety and effectiveness during the expected life time, if the device is used according to the instruction manual.

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Date: Oct 10, 96