

Richard Wolf Medical Instruments Corporation

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510(k) Summary of Safety and Effectiveness

- 1.0 **Classification Name:**
Trocar and Trocar sleeve
- 2.0 **Common/Usual Name:**
Trocar and Trocar sleeve
- 3.0 **Trade Name:**
Pyramidal Trocar with spring-return protective sleeve
- 4.0 **Equivalence:**
These devices are equivalent to existing Richard Wolf Pre-enactment Devices and substantially equivalent to existing competitor devices on the market today.
- 5.0 **Description:**
Trocars are made of medical grade stainless steel and brass (satin chrome-plated).
- 6.0 **Intended Use:**
The pyramidal trocars with spring-return protective sleeve are designed for establishing access by piercing a vessel or chamber to facilitate insertion of the trocar sleeve (cannula) to carry out diagnostic and therapeutic measures.
- 7.0 **Technological Characteristics:**
The trocar was specially designed to shield the tip from exposure after introduction.
- 8.0 **Performance Data:**
Trocars have been tested and found to be safe when used in accordance with the intended use as outlined in the Instruction for Use Manual.
- 9.0 **Clinical Tests:**
No clinical tests performed.

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10.0 Data Conclusion

Trocars from Richard Wolf are substantially equivalent to existing instruments on the market.

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