K960222

510(k) Summary of Safety and Effectiveness

K960222

MAR - 8 1996

1.0 Classification Name:

Orthopedic Manual Surgical Instruments

2.0 Common / Usual Name:

Percutaneous Discectomy System

3.0 Trade Name:

Forceps, dilator, working sleeves, cannulas, trephines, deflectors

4.0 Equivalence:

These devices are equivalent to existing 510(k) Arthroscopy instruments sold by Richard Wolf, Discectomy devices sold by AcuFlex, Smith + Nephew, and Aesculap.

5.0 Description:

Discectomy Instruments are made of medical grade stainless steel. They are used for partial or complete removal of intravertebral disc material in patients suffering from spinal compression syndromes. Percutaneous access is achieved by small incisions and introduction of sleeves.

6.0 Intended Use:

The instruments are used for Percutaneous Lumbar Disc Decompression. This involves partial or complete removal of human intervertebral disc hernias or degenerative diseases within the lumbar region. The goal is to decompress spinal structures like roots of nerves.
Performing procedures like the mentioned PDD (Percutaneous Disc Decompression) is restricted to trained surgeons.
The procedure is normally supported by the use of navigational systems (e.g. CT's, MRI, or Neuronavigation).

7.0 Technological Characteristics:

Basic arthroscopic instruments are equipped with longer shafts and integrated in a set of tubular sheaths to establish access. As the intended use includes punching, grasping, cutting, as well as suction / irrigation, all the functions are provided in the selected instruments.

8.0 Performance Data:

Instruments have been tested to assure there is no breakage of the jaw or other parts of the instrument.

9.0 Clinical Tests:

No Clinical tests were performed.

10.0 Data Conclusion:

The new Richard Wolf Discectomy Instruments are substantially equivalent to existing instruments in the market and have been tested to allow usage with a minimal chance of breakage.

By: Robert L. Casarsa Date: Feb 28 1996

Robert L. Casarsa
Quality Assurance Manager
RICHARD WOLF MEDICAL INSTRUMENT CORPORATION