Richard Wolf Medical Instruments Corporation

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K970345

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: January 24, 1997
Company / Institution name: RICHARD WOLF MEDICAL INSTRUMENTS CORP.			FDA establishment registration number: 14 184 79
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Product Information:

Trade name:	Model number:		
ACL instruments and instrumentation	8869.011	8869.111	8869.151
	8869.152	8869.911	8869.841
	8869.842		
Common name: ACL instruments	Classification name: Endoscope and accessories		

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K940125	1 ACL-Drill Guide Instrument, type 8870.152	1 Richard Wolf
2	2 Alignment instrument, type 8731	2 Linvatec
3	3 Alignment instrument, type AR 1875	3 Arthrex
4	4 Pneumatic drill, type GA 207	4 Aesculap
5	5 Coring Reamer, type AR-1223CR	5 Arthrex
6	6	6

1.0 Description

The ACL instrument by Boszotta allows fast and standardized removal of the patellar ligament by an optimal arthroscopic press-fit technique. The standardized diameter of the bone plugs allows optimum bone contact and promotes rapid healing.

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2.0 Intended Use

The ACL instruments are used for the reconstruction of anterior cruciate ligament with the patellar ligament using the press-fit technique.

- The drill alignment device ensures precise drilling of the tibial channel.
- The pneumatic drill drives the oscillating hollow drills.
- The short hollow drill is used for graft removal from the ligament.
- The long hollow drill with ejector is used for removing the tibial bone plug used for filling in the graft-removal defects on the patella and the tibia.
- The ejector ensures the correct drilling direction and permits subsequent ejection of the bone for the hollow drill.

3.0 Technological Characteristics

- The drill alignment device ensures precise drilling of the tibial channel at an angle of 40-45° to the axis of the tibial shaft to achieve sufficient dorsal positioning of the femoral channel. It includes a small standard drill guide for a drilling wire and a large drill guide for a hollow drill.
- The pneumatic drill works has a 5-cell lamellar motor with oscillation head and finger-controlled speed adjustment. It drives hollow drills with oscillation frequency up to 3400 rpm and oscillating motion angle of ± 20°.
- The hollow drills consist essentially of an oscillating hollow tube, which rotates about its longitudinal axis. Three quarters of the circumference of the cutting edge of the hollow drill is toothed. The segment of the hollow drill facing the ligament is rounded. The closed shape with a scale on the outer surface standardizes the diameter and the removal depth of the bone plugs.

All ACL instruments are autoclavable (steam sterilization) for high hygiene demands.

4.0 Substantial Equivalence

The submitted devices are substantially equivalent to existing 510(k) devices sold by Richard Wolf and/or sold by competitors.

5.0 Performance Data

The ACL Instruments by Boszotta have been used in Eisenstadt Hospital for accident cases for about three years. During this time the instruments were used in more than 200 routine interventions. At this time, no mechanical problems or biological incompatibility reactions have been reported. The steam sterilization following each operation do not show any problems.

6.0 Clinical Tests

No clinical tests performed.

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7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness, when used according to the instruction manual.

By: Robert L Casarsa Date: Jan 24, 97

Robert L. Casarsa
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