

510(k) Summary of Safety and Effectiveness

Submitter:		Date of Preparation: October 17, 1996	
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Product Information:			
Trade name: C-Mount objective lenses, steam-sterilizable		Model number: 85 261.172 85 261.212 85 261.242 85 261.272 85 261.322 85 261.382 85 261.452	
Common name: C-Mount objective lenses		Classification name: Endoscope and/or accessories	
Information on devices to which substantial equivalence is claimed:			
510(k) Number	Trade or proprietary or model name	Manufacturer	
1 pre-enact.	1 RIWO lenses f = 15 mm, 30 mm, 60 mm, Model no. 5400/15, 5400/30, 5400/60	1 Richard Wolf M.I.C.	
2	2 C-mount lenses f = 25 mm, 38 mm, Model no. 20230041, 20230043	2 Karl Storz	
3	3 Coupler 28 mm, 35 mm, , Model no. 88-9714, 88-9715	3 Snowden Pencer	
4	4	4	
5	5	5	
6	6	6	

1.0 Description

The C-Mount objective lenses allows a telescope to be coupled to a video camera.

The focus ring on the objective lenses is rotatable to allow the camera to focus on the telescope to obtain the proper picture.

2.0 Intended Use

The C-Mount objective lenses serve to connect endoscope to video cameras.

The lenses with clamping mechanism are used for video-controlled diagnostics and therapy and allow quick adaptation and fixation of the standard telescopes with eyepiece.

The focus ring serves to focus an endoscopic image on the monitor.

3.0 Technological Characteristics

The C-Mount objective lenses are redesigned for steam sterilization. The production method and function of the device mainly stayed the same.

4.0 Substantial Equivalence

These Devices are substantially equivalent to pre-enactment devices sold by Richard Wolf and to actual 510(k) devices sold by Karl Storz and Snowden Pencer. The differences do not affect safety or effectiveness of the device.

5.0 Performance Data

The devices have been tested to assure that there is no leakage or reduced optical quality when subjected to steam sterilization.

6.0 Clinical Tests

No clinical tests performed.

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
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Date: Oct 16, 1996