

8. 510(K) Summary: K963046

NOV. 1, 1996

Classification Name:

Accessory to Endoscope

Device Trade Name:

500.204 Daycam
& 500.404 Endocam

Sponsor:

Corin U.S.A.
10500 University Center Drive
Suite 130
Tampa, Florida 33612
USA

Reason for Submission:

New device

Intended Use:

Endoscopic video camera to transmit
an image from an endoscope or
arthroscope to a remotely located
video monitor

Major Component:

- Power source
- Video board
- Camera head holding video chip
- Camera cable

Video Data:

- 628 lines resolution
- 0.9 lux minimum illumination
- 1/2" CCD lens
- +6 dB pre-signal conditioning
- Automatic iris 1:16000S

Power Source:

100 - 240V \pm 10% 0 - 440Hz

Safety Testing:

- TUV testing to IEC 601/1 1988
- DIN VDE 0750 TI/12.91
- EMC tested as part of IEC 601/1 1988

The specification of the Corin Endocam & Daycam camera systems are substantially equivalent to the legally marketed Dyonics Digital video camera system in the following areas: Power source, controls, functions, output, iris control, iris shutter speed and light requirement (see 7(g)).

9. Truthful and Accurate Statement:

I hereby confirm that the attached information is, to the best of my knowledge, truthful and accurate.

PRINT NAME: Jack Thomas

SIGNED: 

POSITION: President

DATE: 10 October 1996