

K963043

(g) Detailed Similarities/Differences Comparison:

<u>Endospot 510(k) Device</u>	<u>Autobrite (Predicate Device)</u>
Power Source	Power Source
On/Off Button	On/Off Button
Manual Illumination Control	Manual Illumination Control
Automatic Illumination Control	Automatic Illumination Control
UV/IR Filters	UV/IR Filters
75 Watt	250 Watt
Quartz Halogen Lamp	Quartz Halogen Lamp
2 Lamps in Unit	1 Lamp in Unit
Spare bulb	No spare bulb
Stepless Light Intensity Adjustment	Stepless Light Intensity Adjustment

8. 510(k) Summary:

Classification Name:	Accessory to Endoscope
Device Trade Name:	Endospot
Sponsor:	Corin U.S.A. 10500 University Center Drive Suite 130 Tampa, FL 33612 USA
Reason for Submission:	New device
Intended Use:	Endoscopic light source to provide illumination for fibre optic endoscopy to joint cavities and abdominal space.
Major Components:	- Power Source - Quartz Halogen Lamp - Lamp illuminator adjuster
Lamp/Data	- Light intensity 75W - Lamp life - 50 hours full power 200 hours in lamp save mode - Color temperature - 3200K
Power Source:	100 - 240V ± 10% 0 - 440 Hz
Safety Testing:	- TUV tested to IEC 601/1 1988 - DIN VDE 0750 TI/11.91 - Electromagnetic compatibility tested

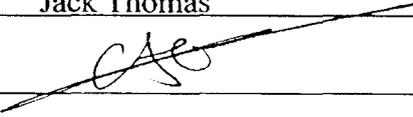
Comparison to Legally Marketed Endoscopic Light Source:

3180 Auto Brite Illuminator II  
Smith and Nephew Dyonics  
160 Dascomb Road  
Andover, Massachusetts 01810  
USA

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: 1 August 1996