

UROHEALTH Systems, Inc.
Costa Mesa, CA

MAR 12 1997

K970598/S001
P172
510(k) Notification
Integrated Visualization System
February 17, 1997

510(k) SUMMARY

COMPANY NAME AND ADDRESS

UROHEALTH Systems, Inc.
3050 Redhill Ave.
Costa Mesa, CA. 92626

CONTACT PERSON

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Corporate Director, Regulatory Affairs

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DEVICE TRADE NAME

Integrated Visualization System

COMMON NAME

Light Source, Camera, and Monitor in one unit

PREDICATE DEVICE

1. Device Name: Welch Allyn Hi - Lux Illuminator
Classification: II
Manufacturer: Welch Allyn
510(k) #: K951647

2. Device Name: Integrated Video System
Classification: II
Manufacturer: BEI Medical Systems Company, Inc.
510(k) #: unknown

3. Device Name: Camera, Accessory to endoscope
Classification: I
Manufacturer: Corin U.S.A.
510(k) #: K963046

DEVICE DESCRIPTION

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The Integrated Visualization System is comprised of a light source, CCD camera, and 10.4" flat panel monitor, all housed in a single unit weighing approximately seven pounds. It has an immersible camera head with minimum illumination requirements of ≤ 1 lux. The light source uses 24 watts and outputs a color temperature of 5460°K.

INDICATIONS FOR USE

The IVS is used in providing illumination for endoscopic procedures and transmitting an image from an endoscope to a viewing monitor, which is integral to the system.

BIOCOMPATIBILITY

The materials and components of the proposed Integrated Visualization System do not have patient or body fluid contact and therefore biocompatibility testing is not applicable.