

# IMAGE1 S™ RUBINA™

4K Fluorescence Imaging with ICG –  
The Value of One



FOR U.S. USE ONLY

**STORZ**  
KARL STORZ — ENDOSKOPE

# IMAGE1 S™ RUBINA™

## 4K Fluorescence Imaging with ICG – The Value of One

There are exciting advancements that are happening in the OR around the NIR/ICG technology. Below are the 510K submissions to help you better understand what systems can perform which procedure based on their APPROVED Indications for Use.

Indication for Use*	KARL STORZ IMAGE1 S™ RUBINA™ (K202925)	K202592	K182606	K202244	K200542	K191851	K141077
Bile Duct Identification (BDI)	●	●	●		●		●
Perfusion	●	●	●	●	●		●
Neuro Surgery	●						
Open Procedures	●	●		●			
Sentinel Lymph Node (SLN)	●	●	●	●		●	

\*Information from FDA Center for Devices and Radiological Health. Details on 510(k) premarket notifications can be found at [www.fda.gov/medical-devices](http://www.fda.gov/medical-devices).

As the table shows, separate systems from the same manufacturer are not always compatible—which means it might not be a simple matter to combine them. To get the broadest, most reliable coverage, it makes sense to stick with a single system from a single supplier—such as the 4K NIR/ICG system IMAGE1 S™ RUBINA™. This advanced system enables minimally invasive surgery using standard white light as well as visual assessment of bile ducts using near-infrared. It’s also indicated for use in minimally invasive cranial neurosurgery and in evaluating blood flow and tissue perfusion. Finally, it now offers the ability to identify sentinel lymph nodes and lymphatic vessels.

## K202925

### KARL STORZ RUBINA™ NIR/ICG Imaging System

Upon intravenous administration and use of ICG consistent with its approved label, the KARL STORZ Endoscopic ICG System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging. Fluorescence imaging of biliary ducts with the KARL STORZ Endoscopic ICG System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

Additionally, the KARL STORZ Endoscopic ICG System enables surgeon to perform minimally invasive cranial neurosurgery in adults and pediatrics and endonasal skull base surgery in adults and pediatrics > 6 years of age using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion using near infrared imaging.

The KARL STORZ VITOM® II ICG System is intended for capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures. The VITOM® II ICG System is intended to provide a magnified view of the surgical field in standard white light.

Upon interstitial administration and use of ICG consistent with its approved label, the KARL STORZ Endoscopic ICG System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.



**KARL STORZ OPAL1° NIR/ICG system – K180146**

The KARL STORZ NIR/ICG system is intended to provide real-time visible (VIS) and near-infrared (NIR) fluorescence imaging.

## **K202592**

### **STRYKER 1688 Camera Control Unit; 1688 AIM 4K Camera Head, C-Mount; 1688 AIM 4K Camera Head with Integrated Coupler; AIM 4K Coupler, 20 mm, C-Mount; L11 LED Light Source with AIM – K202592**

The 1688 Video Camera is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery whenever a laparoscope/ endoscope/ arthroscope is indicated for use. A few examples of the more common endoscope surgeries are Laparoscopic cholecystectomy, Laparoscopic hernia repair, Laparoscopic appendectomy, Laparoscopic pelvic lymph node detection, Laparoscopically assisted hysterectomy, Laparoscopic and thorascopic anterior spinal fusion, Anterior cruciate ligament reconstruction, Knee arthroscopy, Small joint arthroscopy, Decompression fixation, Wedge resection, Lung biopsy, Pleural biopsy, Dorsal sympathectomy, Pleurodesis, Internal mammary artery dissection for coronary artery bypass, Coronary artery bypass grafting where endoscopic visualization is indicated and Examination of the evacuated cardiac chamber during performance of valve replacement. The users of the 1688 Video Camera are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

#### **L11 LED Light Source with Advanced Imaging Modality**

Upon intravenous administration of SPY AGENT™ GREEN (Indocyanine green for injection, USP), the AIM Light Source and SafeLight™ Cable is used with SPY AGENT GREEN to provide real-time endoscopic visible and near infrared fluorescence imaging. The AIM Light Source and SafeLight Cable enable surgeons to perform minimally invasive surgery using standard endoscope visual light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near-infrared imaging.

Fluorescence imaging of biliary ducts with the AIM Light Source and SafeLight Cable is intended for use with standard-of-care white light and, when indicated, intraoperative cholangiography. The devices are not intended for standalone use for biliary duct visualization.

Upon interstitial administration of SPY AGENT GREEN (ICG drug product), the AIM Light Source and SafeLight™ Cable is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes. The AIM Light Source is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

## **K182606**

### **PINPOINT Endoscopic Fluorescence Imaging System**

Upon intravenous administration of TRADENAME (ICG drug product), the PINPOINT Endoscopic Fluorescence Imaging System is used with TRADENAME to perform intraoperative fluorescence angiography, and it is also indicated for use in fluorescence imaging of biliary ducts, and when indicated, during intraoperative cholangiography.

The PINPOINT Endoscopic Fluorescence Imaging System is indicated for use to provide real time endoscopic visible and near-infrared fluorescence imaging. The PINPOINT System enables surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using nearinfrared imaging.

Fluorescence imaging of biliary ducts with the PINPOINT System is intended for use with standard of care white light, and when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

Upon interstitial administration of TRADENAME (ICG drug product), the PINPOINT System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

## **K202244**

### **SPY Portable Handheld Imaging (SPY-PHI) System**

Upon intravenous administration of SPY AGENT™ GREEN (indocyanine green for injection, USP) the SPY-PHI System is used with SPY AGENT™ GREEN to perform intraoperative fluorescence angiography. The SPY-PHI System is indicated for use in adult and pediatric patients one month of age and older.

The SPY-PHI System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgical procedures.

Upon interstitial administration of SPY AGENT™ GREEN, the SPY-PHI System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

## **K191851**

### **Medtronic EleVision VS3-IR system**

Upon intravenous administration and use of an ICG consistent with its approved label, the Iridium Module of the VS3-IR System is used to perform intraoperative fluorescence angiography.

Upon interstitial administration and use of ICG consistent with its approved label, the Endoscope configuration of the VS3-IR System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

## **K141077**

### **Intuitive da Vinci Firefly Imaging System**

The da Vinci Firefly™ Imaging System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The da Vinci Firefly™ Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near infrared imaging.

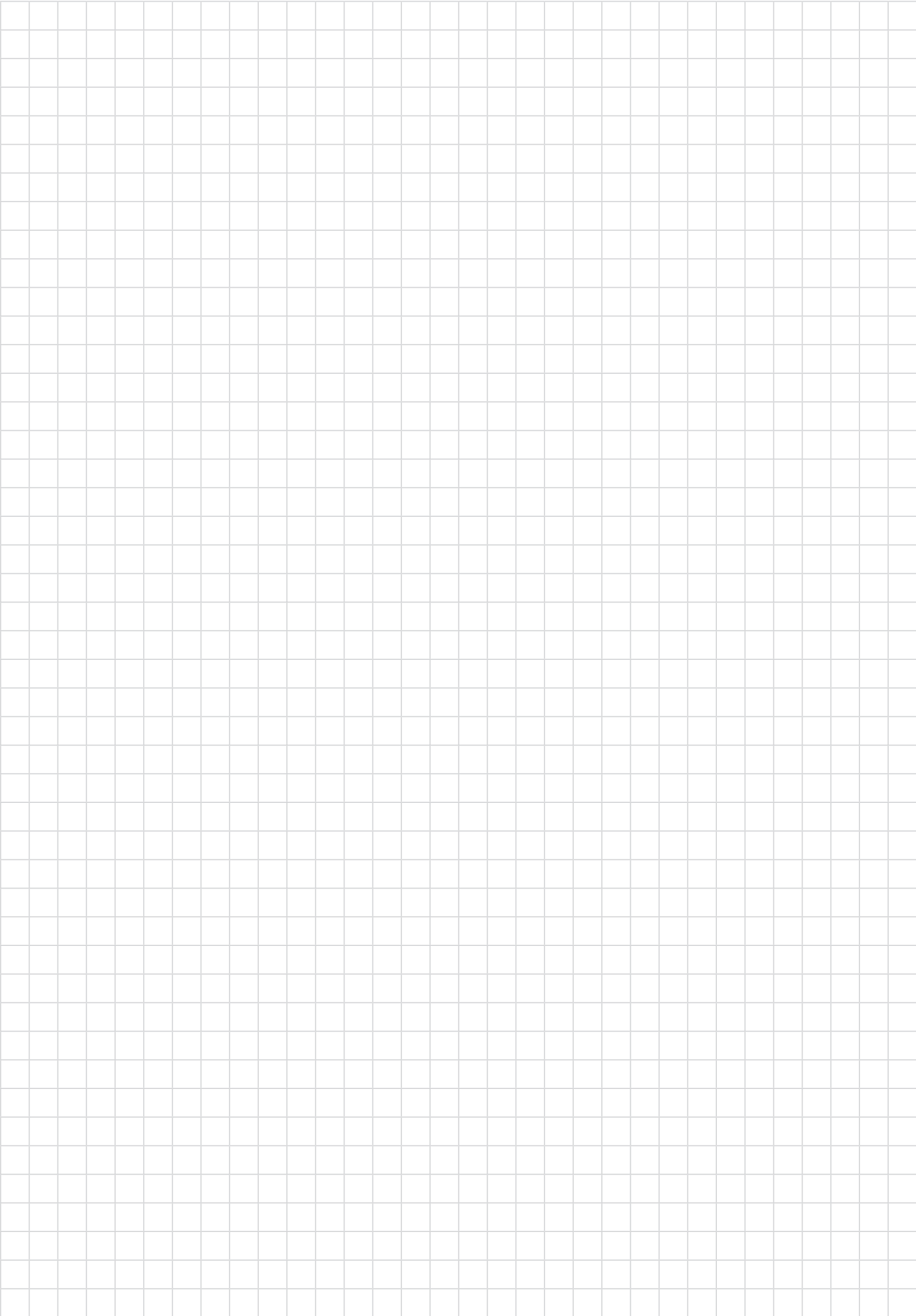
Fluorescence imaging of biliary ducts with the da Vinci Firefly™ Imaging System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

## **K200542**

### **VISERA ELITE II Infrared Imaging System**

The VISERA ELITE II Infrared Imaging System is intended to provide real-time endoscopic visible and near infrared fluorescence imaging. The VISERA ELITE II Infrared Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near-infrared imaging. Fluorescence imaging of biliary ducts with the VISERA ELITE II Infrared Imaging System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

**Notes**



More than  
**75**  
Years

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of Endoscopy with you*

KARL STORZ Endoscopy-America, Inc.  
2151 East Grand Avenue  
El Segundo, CA 90245-5017, USA  
Phone: +1 424 218-8100  
Phone toll free: 800 421-0837 (US only)  
Fax: +1 424 218-8525  
Fax toll free: 800 321-1304 (US only)  
E-Mail: [communications@karlstorz.com](mailto:communications@karlstorz.com)

**STORZ**  
KARL STORZ—ENDOSKOPE

THE DIAMOND STANDARD

KARL STORZ SE & Co. KG  
Dr.-Karl-Storz-Straße 34, 78532 Tuttlingen/Germany  
Postbox 230, 78503 Tuttlingen/Germany  
Phone: +49 7461 708-0  
Fax: +49 7461 708-105  
E-Mail: [info@karlstorz.com](mailto:info@karlstorz.com)  
[www.karlstorz.com](http://www.karlstorz.com)

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