Medical Information Technologies
FDA Classification

February 2010

EndoWorks is a Class 1 Medical Device as defined by the FDA. A Class 1 Medical Device represents the lowest patient risk device class. Consistent with EndoWork's current classification as a Class 1 device, EndoWorks is a 510(k) exempt device and changes to the EndoWorks product do not require a new 510(k) notification or clearance in advance of marketing and distribution. Please note that unique to EndoWorks and Olympus' early role in marketing an endoscopic image management system, FDA did require a 510(k) for the EndoWorks product when this product was first marketed in the early 1990s. As a result, Olympus has a number of cleared 510(k)s on the EndoWorks product. However, in 2000, the FDA reclassified this device and subsequently exempted the product from further 510(k) notification requirements.

EndoWorks has been designed, developed and validated to work with specified computer hardware, such as hard drives, printers and monitors. When such general-purpose computer hardware is integrated into a medical device, these general-purpose hardware products become part of our EndoWorks medical device. To assure the highest level of quality to our users and to assure EndoWorks performs as designed, Olympus tests the software in conjunction with specified hardware platforms. The Olympus EndoWorks system is marketed (sold) with hardware to provide further assurances of quality and reliability to the user.