March 6, 2015

News Release

Company: Olympus Corporation
Representative Director, President: Hiroyuki Sasa
(Code: 7733, TSE First Section, Tokyo Stock Exchange)
Contact: Tetsuo Hyakutake, General Manager, Public Relations & IR Office

Notice Concerning Media Reports on Our Duodenoscope in the U.S.

Media in the U.S. and other countries has reported that an OLYMPUS duodenoscope, specifically model TJF-Q180V, has been marketed in the U.S. since 2010 without a 510(k) clearance by the U.S. Food and Drug Administration (FDA) for sale to hospitals and other licensed medical facilities.

Olympus Medical Systems Corporation (OMSC) made a decision, based upon FDA policy, that a modification to our previously FDA cleared duodenoscope did not require a new 510(k) application to FDA prior to marketing the modified duodenoscope in the U.S. in 2010.

As a medical device manufacturer, we remain committed to serving people worldwide by contributing in a meaningful and positive way to the healthcare environment, working in each country to adhere strictly to local regulations, follow sound business practices and conduct our business according to society's expectations.

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