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510(k) SUMMARY

OLYMPUS ENDOSCOPIC SYSTEM FOR VESSEL HARVESTING

Device Name: Olympus Endoscopic System for Vessel Harvesting: endoscope, associated accessories and ancillary equipment.

Common/Usual Name: Olympus Endoscopic System for Vessel Harvesting

Classification Name: Endoscope and Accessories

Predicate Devices: Olympus Endoscopes for Subcutaneous Dissection/Resection in Plastic/Reconstructive Surgery and Aesthetic Surgery (K950076); Olympus Hand Instruments for Subcutaneous Dissection/Resection in Plastic/Reconstructive Surgery and Aesthetic Surgery (K950103); Ethicon EndoSurgery Hand Retractors, Dissectors for Vessel Harvesting (K955120). Refer to Subsection I-A for additional list of predicate devices.

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Statement of Intended Use

The Olympus Endoscopic Vessel Harvesting System is specifically designed for subcutaneous endoscopy - - more specifically for endoscopically gaining access to, ligating and/or harvesting vessels (e.g. veins, arteries, ducts, nerve) within the subcutaneous and subfacial surgical planes in the lower extremities.

Comparison to Predicate Device

The Endoscopic Vessel Harvesting System is identical or similar in design, function, and intended use to the Olympus Endoscopes for Subcutaneous Dissection/Resection in Plastic/Reconstructive Surgery and Aesthetic Surgery (K950076), Olympus Hand Instruments for Subcutaneous Dissection/Resection in Plastic/Reconstructive Surgery and Aesthetic Surgery (K950103), and Ethicon EndoSurgery Hand Retractors, Dissectors for Vessel Harvesting (K955120). Thus, when compared to the predicate devices, the Olympus System for Vessel Harvesting does not raise any questions regarding the safety of the subject device.