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510(k) Summary

K930666

Submitter:

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Trade Name - Diamond-Touch® and Micro Diamond-Touch® Instruments; Diamond-Line®
Instruments; Diamond Port (Access Ports); Endo CABG (TM Approval Pending); CARDIO
Port (TM Approval Pending)

Common Name - Endoscope and Accessories for Minimally Invasive Cardiovascular Surgery

Classification Name - Endoscope and Accessories (per 21 CFR 876.1500)

Equivalent Device - Snowden-Pencer 510(k) # K930666 - Reusable Laparoscopic/Endoscopic
Surgical Instruments with Electrosurgical Connections and Accessories and Snowden-Pencer
510(k) # K930667 -- Reusable Laparoscopic/Endoscopic Surgical Instruments for General
Surgery, and Plastic and Reconstructive Surgery, Including Aesthetic Surgery

Device Description - The devices are separated into several groups: endoscopes, endoscopic
needle holders, endoscopic graspers and clamps, endoscopic scissors, endoscopic knife blade
handles, hooks and clip applicators, endoscopic irrigation/aspiration probes, endoscopic
electrodes, retractors and rib spreaders, thoraports and cannulas.

Intended Use - Various endoscopic surgical instruments for use in minimally invasive cardiac
procedures including single bypass and multiple bypass (coronary artery bypass grafting
(CABG)procedures), and saphenous vein harvesting.

Summary of Technical Characteristic Equivalence - The endoscopes and endoscopic surgical
instruments for cardiac procedures will use equivalent materials (such as stainless steel,
titanium, rigid and flexible plastics, and insulation) and use the same designs (same handles,
tubes, and jaws) as our current marketed line of general and plastic surgery endoscopes and
endoscopic surgical instruments.

Summary of Performance Equivalence - The endoscopes and endoscopic surgical instruments for
cardiac procedures will have equivalent performance standards to our currently marketed line
of general and plastic surgery endoscopes and endoscopic surgical instruments.