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SUMMARY OF SAFETY AND EFFECTIVENESS
CFR 807.92(c)

1. INDICATIONS: The indications or intended use for the DLP Octopus[tm] Tissue Stabilizer and the predicate product, Cardiothoracic Systems, Inc. (CTS) Thoracic Access Platform and Stabilizer are the same. Both are intended for use du ring coronary artery bypass grafting to isolate diseased artery and minimize motion of the beating heart to facilitate the grafting procedure.

2. DESIGN: The design of the Octopus[tm] is similar to both predicate products referenced in the Comparison Information Section. It features plastic handle with vacuum tubing connection, malleable stainless steel arm and suction tip similar to the DLP Cardiac Suction Tube product. The "feet" design of the Octopus[tm] is intended to position the anastomosis site between two "feet" for isolation and stabilization control which is the same as the CTS Thoracic Access Platform and Stabilizer.

3. MATERIALS: The contact surface of the Octopus[tm] feet or tentacles on the heart is a plastic material that has been biocompatibility tested.

4. SAFETY AND EFFICACY: No differences in safety and efficacy. Materials have undergone acceptable biocompatibility testing. Intended use is same as CTS Stabilizer predicate product. Design characteristics are similar to both DLP Cardiac Suction and CTS Stabilizer predicate products.

5. DIFFERENCES: Primary differences between Octopus[tm] and CTS Stabilizer is the Octopus[tm] functions by applying controlled suction to the myocardium whereas the CTS Stabilizer applies random amount of pressure.

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