510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

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Trade Name:	Reprocessed HARMONIC ACE®+ 7 Shears with Advanced Hemostasis (Models HARH23R and HARH36R)
Regulation Name:	Scalpel, Ultrasonic, Reprocessed
Device Classification:	Unclassified
Product Code	NLQ
Predicate Device:	HARMONIC ACE®+7 Shears with Advanced Hemostasis (Ethicon K132612 - Models HARH23 and HARH36)
Device Description:	The Sterilmed Reprocessed HARMONIC ACE+7 Shears with Advanced Hemostasis are used for coagulation and mechanical transection of soft tissue during laparoscopic and open procedures. The devices allow the surgeon to grasp, coagulate, and transect soft tissue with a single instrument. The devices are hand-actuated with a shaft and tissue effector that can be rotated. The energy delivery can be activated with hand activation or with an optional generator foot switch. The two models are identical to each other in materials, form, fit and function except for the length of the shafts which are 23cm and 36 cm.
Model Numbers	HARH23R (shaft length 23 cm) HARH36R (shaft length 36 cm)
Indications For Use:	The Sterilmed Reprocessed HARMONIC ACE+ 7 Shears with Advanced Hemostasis are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for

	electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter using the Advanced Hemostasis hand control button.
Technological Characteristics:	The Reprocessed HARMONIC ACE+ 7 Shears with Advanced Hemostasis has the same technological and performance characteristics as the predicate device HARMONIC ACE+ 7 Shears with Advanced Hemostasis (K132612). The subject devices use an EEPROM memory chip that stores device identification, usage tracking, and operating parameters for use by the Generator G11 that provides power for the Reprocessed HARMONIC ACE+ 7 Shears with Advanced Hemostasis. The devices have an ergonomic grip housing assembly with hand control buttons (MIN for minimum power level, MAX for maximum power level, and Advanced Hemostasis for large vessel [up to 7 mm] sealing). Adaptive Tissue Technology refers to the power output algorithm that is utilized by the devices. During use, the Adaptive Tissue Technology algorithm parameters stored on the device EEPROM are read by the generator and used to reduce the power (current) to the instrument and provide a secondary, higher pitched generator activation tone as Adaptive Tissue Technology regulates the delivery of energy. To do this the generator monitors the thermal condition of the blade during device activation. The Advanced Hemostasis mode utilizes a unique algorithm within Adaptive Tissue Technology that modulates the power delivery from the Generator G11 to the blade of the device maximizing hemostasis.
Functional and Safety Testing:	Representative samples of reprocessed devices were tested to demonstrate appropriate functional characteristics. Process validation testing was performed to validate cleaning and sterilization as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced. Where appropriate, prior validation testing of previously cleared Reprocessed HARMONIC Shears: ACE- (K132566) or Reprocessed HARMONIC Shears: ACE + (K161086) was utilized as the devices are substantially equivalent. The Reprocessed HARMONIC Shears with Advanced Hemostasis: ACE + 7, are reprocessed no more than one (1) time. The torque wrench accessories are reprocessed no more than five (5) times. Each device and accessory are marked and tracked through the

	reprocessing cycle. After the device or torque wrench has reached the maximum number of reprocessing cycles, one and five, respectively, it is rejected from further reprocessing.
Summary of Non-Clinical Tests Conducted:	Specific non-clinical tests performed included: cleaning validation, sterilization verification, ethylene oxide residual testing (ISO 10993-7), packaging validation (ASTM D4169, ASTM F88, ASTM F2096), and shelf-life validation (ASTM 1980-07). In addition, validation of functional performance (bench testing) was performed through simulated use, visual inspection, and fatigue testing. Testing performed: • Electrical Safety • Vein Seal Burst (1-7mm) and Tissue Adhesion • Artery Seal Burst (1-7mm) and Tissue Adhesion • Lymphatics Seal Performance • Vessel Seal Thermal Spread • Drop • Fluid Ingress • Pad Retention • Pad Life • Grasping Force Performance testing shows the Reprocessed HARMONIC ACE+ 7 Shears with Advanced Hemostasis performs as originally intended. In addition, the device was tested for biocompatibility per ISO 10993-1 for external communicating device, short duration contact with circulating blood (<24 hours). Biocompatibility testing included: • Cytotoxicity • Sensitization • Irritation/Intracutaneous Reactivity • Acute Systemic Toxicity • Pyrogenicity
Conclusion:	Sterilmed conducted performance testing for the Reprocessed HARMONIC ACE+ 7 Shears with Advanced Hemostasis against the OEM predicate device, HARMONIC ACE+ 7 Shears with Advanced Hemostasis (K132612). Results demonstrated substantial equivalence to the predicate devices with respect to safety and effectiveness. Sterilmed therefore concludes that the Reprocessed HARMONIC ACE+ 7 Shears with Advanced Hemostasis is safe, effective, and substantially equivalent to the predicate device, HARMONIC ACE+ 7 Shears with Advanced Hemostasis.