DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K182272

Device Name
Sterilmed Reprocessed HARMONIC ACE®+ 7 Shears with Advanced Hemostasis (Models HARH23R and HARH36R)

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Ethicon OEM Model #	Sterilmed Model #	Description
HARH23	HARH23R	Reprocessed HARMONIC ACE+ 7 Shears with Advanced Hemostasis, 23 cm Length
HARH36	HARH36R	Reprocessed HARMONIC ACE+ 7 Shears with Advanced Hemostasis, 36 cm Length