Class 2 Device Recall SERFAS 90 degree Energy Probe, Part Number 279350101

See Related Information[23]

Date Posted	June 24, 2015
Recall Status[1]	Open
Recall Number	Z-1831-2015
Recall Event ID	71385[24]
Premarket Notification 510(K) Number	K041810[25]
Product Classification	Electrosurgical, Cutting & Coagulation & Accessories[26] - **Product Code** GEI[27]
Product	SERFAS 90 degree Energy Probe, Part Number 279-350-101; SERFAS Energy Probes are indicated for arthroscopic procedures of the knee, shoulder, ankle, hip, elbow and wrist. Specifically, the probes are used for resection, ablation and coagulation of soft tissue, as well as the hemostasis of blood vessels.
Code Information	Part number 279-350-101; All non expired product; lot numbers 13128AE2 through 14337AE2.
Recalling Firm/ Manufacturer	Stryker Endoscopy 5900 Optical Ct San Jose, California 95138-1400
For Additional Information Contact	Michael Hilldoerfer 408-754-2664
Manufacturer Reason for Recall	Stryker Endoscopy is recalling all non expired SERFAS 90 degree Energy Probes due to reports of fragments of the probe breaking off into the patient.
FDA Determined Cause [2]	DESIGN: Device Design
Action	Stryker sent an Urgent Medical Device Recall letter dated June 5, 2015, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to do the following: 1. Inform individuals within their organization who need to be aware of this device removal. 2. Review inventory of lots of part number 279-350-101 and determine if you have the affected product (all non-expired devices) in stock. Response is required. 3. If no product is found, complete acknowledgement form located on the Stryker Endoscopy recall website endorecall.stryker.com by logging in using the account number and zip code on this letter. 4. If you do have product, segregate the product and call Stryker customer service at 1-800-624-4422 Option 3 to arrange for product return and issuance of credit. For questions regarding this recall call 408-754-2664.
Quantity in Commerce	22,063 devices
Distribution	Worldwide Distribution - US (nationwide) and Internationally to US Argentina, Australia, Bolivia, Brazil, Chile, China, Colombia, Hong Kong, India, Italy, Japan, Republic of Korea, Malaysia, Netherlands, Poland, Romania, Singapore, South Africa, Spain, Sweden, Switzerland, United Arab Emirates, and United Kingdom.
Total Product Life Cycle	TPLC Device Report[28]