



A Hologic Company

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Dear Valued Customer,

This summer, the Food and Drug Administration (FDA) issued a safety communication to physicians regarding concerns about “vaginal rejuvenation” procedures that use energy-based devices. As the leading global women’s health company, Hologic took these concerns seriously and acted swiftly with an abundance of caution and care for patients and practices as we gained a deeper understanding of FDA’s perspective on this issue. This letter is intended to share an update with you regarding key milestones and activities about the MonaLisa Touch® CO2 Laser (MLT).

- **July 30, 2018-** Safety communication issued by FDA to physicians with a press release to the media. Cynosure received an “It Has Come to Our Attention” (IHCTOA) letter questioning marketing claims, along with 6 other competitors that also received letters. Our letter did not challenge the safety of MLT but did question whether or not our existing 510(k) clearance adequately covered some of the claims located on our website/marketing materials. Specific questions in Cynosure’s IHCTOA letter can be found on the FDA website:
<https://www.fda.gov/medicaldevices/resourcesforyou/industry/ucm111104.htm>
- **August – October 2018-** We remained in contact with the FDA regarding marketing claims for MLT and revised our materials to address their concerns. Also, Hologic’s Clinical and Regulatory leadership met with FDA to discuss clinical strategies for gathering data and studying the impact of MLT’s fractional CO2 energy on gynecologic tissue.
- **November 9, 2018-** Cynosure received confirmation from FDA that we had adequately addressed all the issues raised in the IHCTOA letter.

We were very pleased to receive the November 9th notice from FDA confirming their agreement that all refreshed marketing claims on Hologic’s US websites align to the 510(k) clearance under which MonaLisa Touch operates, which includes gynecologic use in the US. The 510(k) clearance reads:

The SMARTXIDE2 Laser System (MLT) was cleared on September 5, 2014 by the FDA for indications that include gynecology applications; specifically, incision, excision, ablation, vaporization, and coagulation of the body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology, gynecology, neurosurgery, orthopedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery, and genitourinary surgery. Use with the scanning unit is indicated for ablative skin resurfacing.

Given our strength in women’s health and our ongoing progress in developing sham-controlled clinical studies to further demonstrate the clinical value of MonaLisa Touch, we are well-poised to be a leader in this area. Hologic shares the same goals as FDA – clinically strong products that improve patient lives and are marketed responsibly. Just as we approach all our products, we are fully committed to marketing in compliance with FDA requirements and believe this higher level of scrutiny from regulatory authorities will benefit both our customers and our patients.

If you have additional questions call (844) 365-5060 or email cynosureclinicalsupport@Hologic.com.