

510(k) K163288

K-fit received 510(k) clearance from the FDA with the following indications for use:

K-fit Kegel Toner (Model: KM518) is a non-implanted muscle stimulator designed to treat stress, urge and/or mixed urinary incontinence in women. It applies stimulation to the pelvic floor muscles and surrounding structures to improve strength and support.

FDA cleared for over-the-counter dispensing without a prescription.

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