Erchonia FDA 510(k) Indications for Use Updated 01/25/2023			
1.	Indication – <i>Chronic neck and shoulder pain</i>		
	• January 17 th , 2002	• FDA Market Clearance K012580	
	• Device – Red single diode	• Results Published - Funct Neurol Rehabil Ergon 2016;6(2):97-104	
2.	Indication Low Level Laser Assisted Liposuction and reduction of pain associated with surgery		
	• September 30 th , 2004	• FDA Market Clearance K041139	
	• Device – Red multi-diode	Results Published - The American Journal of Cosmetic Surgery	
3.	Indication – Erchonia EVRL – a. while using the red diode, for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin, b		
	b. and while using the violet diode, to treat dermatological conditions, and specifically indicated to treat moderate inflammatory Acne Vulgaris		
	• May 2 nd , 2005	FDA Market Clearance K050672	
	• Device – Red/Violet multi-diode	Results Will Not be Published	
4.	Indication – Breast Augmentation and Pain Associated with Surgery		
	• April 24 th , 2008	FDA Market Clearance K072206	
	Device – Multi-diode red Cosmetic Surgery	Results Published - Breast Augmentation American Journal of	
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5.	 Indication – <i>Non-Invasive Body Contouring and Fat Reduction</i> August 28th, 2010 	• FDA Market Clearance K082609	
	 Device – Erchonia MLS Scanner (Zerona) 	Results Published - Lasers in Surgery and Medicine 41:799–809	
	(2009)		
6.	Indication – Arm Circumference Reduction of the Upper Arms		
	• May 14 th , 2012	FDA Market Clearance K121690	
	• Device – Erchonia MLS Scanner (Zerona)	Results Published - Seminars in Cutaneous Medicine and Surgery	
7.	Indication – <i>Reduction in the Appearance of Cellulite</i>		
	 May 17th, 2013 Device – Erchonia Verju Laser System with Massager 	 FDA Market Clearance K130922 Results Published - Lasers in Surgery and Medicine 	
	• Device – Elenomia verju Laser System with Massager • Results i ubrished - Lasers in Surgery and Medicine		
8.	Indication – Non-invasive Body Contouring of the Waist, Hips and		
	 May 17th, 2013 Device – Erchonia Verju Laser System with Massager 	 FDA Market Clearance K130922 Results Published - American Journal of Cosmetic Surgery 	
9.	Indication – <i>Adjunct to Chronic Heel Pain Arising from Plantar F</i> . • April 14 th , 2014		
	 April 14th, 2014 Device – Erchonia ALLAY (FX 635 Laser) 	 FDA Market Clearance - K132940 Results Published - American Orthopaedic Foot & Ankle Society 	
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10.	 Indication – <i>Non-Invasive Body Contouring of the Waist, Hips and</i> October 21st, 2014 	 <i>Upper Abdomen for BMI 30-40</i> FDA Market Clearance K142042 	
	 Device – Erchonia SHL (10 Head) 	Results Published - Photomedicine and Laser Surgery	
11	Indication – Zerona-Z6 OTC - Non-Invasive Dermatological Aesthetic Treatment for the reduction of the circumference of the hips,		
11.	waist and thighs		
	• January 15 th , 2015	FDA Market Clearance K143007	
	• Device – Zerona-Z6	Results Will Not be Published	
12.	Indication – Zerona-Z6 (6) Week Protocol - Non-Invasive Dermatological Aesthetic Treatment for the Reduction of Circumference of Hips, Waist, Thighs and Upper Abdomen (1 Tx per Week for 6 Weeks)		
	 May 21st, 2015 Device - Zerona-Z6 	 FDA Market Clearance K150446 Results Published – The Journal of Clinical & Aesthetic 	
	Dermatology	results i ublished – i në journal të Chineai & Aesthetie	
13	Indication - The LunulaLaser device is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g.,		
15.	dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.)		
	• June 3 rd , 2016	• FDA Market Clearance K153164	
	Device-Erchonia Lunula Laser	Results Published - Journal of Clinical and Aesthetic Dermatolgy	
14.	Indication - <i>The ZERONA Z6 OTC Laser is indicated for use as a body circumference.</i>	non-invasive dermatological aesthetic treatment for the reduction of	

*body circumference.*December 16th, 2016

• Device-Erchonia Zerona Z6 OTC

- FDA Market Clearance K162578
- Results Will Not be Published

- 16. Indication The FX-635 laser is indicated for the adjunctive use in providing temporary relief of nociceptive musculoskeletal pain. June 1st, 2019 • FDA Market Clearance K190572 Device-Erchonia FX 635 • Results Published Orthopedics and Rheumatology Journal 17. Indication - Erchonia EVRL while using the red and violet diode simultaneously, for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin, and while using the violet diode, to treat dermatological conditions, and specifically indicated to treat moderate inflammatory Acne Vulgaris August 8th, 2019 • FDA Market Clearance K191257 • • Results Published Medical Devices: Evidence and Research Device - Red/Violet multi-diode • 18. Indication - Emerald Laser is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference in individuals with a Body Mass Index (BMI) up to 40 kg/m2 September 13th, 2019 • FDA Market Clearance K192254 • • Device-Erchonia Emerald Laser (SHL) • Results Will Not be Published
- 19. Indication Erchonia Red Laser is indicated as an adjunctive treatment of postoperative pain
 - October 22, 2021
 - Device - Red multi-diode
- 20. Indication Erchonia FX-405 Laser is indicated for relief of nociceptive musculoskeletal pain. November 12th, 2021
 - Device Red/Violet multi-diode •

FDA Market Clearance K212595

• FDA Market Clearance K211186

· Results Submitted to be Published

• Results Will Not be Published

- 21. Indication Erchonia GVL
 - while using the green and violet diode simultaneously, for adjunctive use in providing temporary relief of minor chronic neck a. and shoulder pain of musculoskeletal origin,
 - and while using the violet diode, to treat dermatological conditions, and specifically indicated to treat moderate inflammatory b. Acne Vulgaris
 - September 1st, 2022
 - Device Green/Violet multi-diode

- FDA Market Clearance K221987
- Results Will be Published

- 15. Indication The FX 635 laser is indicated for the following two indications:
 - a. as an adjunct to provide relief of minor chronic low back pain of musculoskeletal origin.
 - b. as an adjunct to reducing chronic heel pain arising from plantar fasciitis. •
 - May 21st, 2018

a.

b.

Device-Erchonia FX 635

- FDA Market Clearance K180197
- Results Published eMedical Research & Journal of Pain & Relief