Erchonia FDA 510(k) Indications for Use *Updated 01/25/2023*

1. Indication – ***Chronic neck and shoulder pain***
   - January 17th, 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 30th, 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. and while using the violet diode, to treat dermatological conditions, and specifically indicated to treat moderate inflammatory Acne Vulgaris
   - May 2nd, 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   - Device – Red/Violet multi-diode • Results Will Not be Published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 24th, 2008 • FDA Market Clearance K072206
   - Device – Multi-diode red • Results Published - Breast Augmentation American Journal of Cosmetic Surgery

5. Indication – ***Non-Invasive Body Contouring and Fat Reduction***
   - 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 14th, 2012 • FDA Market Clearance K121690
   - Device – Erchonia MLS Scanner (Zerona) • Results Published - Seminars in Cutaneous Medicine and Surgery

7. Indication – ***Reduction in the Appearance of Cellulite***
   - May 17th, 2013 • FDA Market Clearance K130922
   - Device – Erchonia Verju Laser System with Massager • Results Published - Lasers in Surgery and Medicine

8. Indication – ***Non-invasive Body Contouring of the Waist, Hips and Thighs***
   - May 17th, 2013 • FDA Market Clearance K130922
   - Device – Erchonia Verju Laser System with Massager • Results Published - American Journal of Cosmetic Surgery

9. Indication – ***Adjunct to Chronic Heel Pain Arising from Plantar Fasciitis***
   - April 14th, 2014 • FDA Market Clearance - K132940
   - Device – Erchonia ALLAY (FX 635 Laser) • Results Published - American Orthopaedic Foot & Ankle Society

10. Indication – ***Non-Invasive Body Contouring of the Waist, Hips and Upper Abdomen for BMI 30-40***
    - October 21st, 2014 • 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, waist and thighs***
    - January 15th, 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 • FDA Market Clearance K150446
    - Device – Zerona-Z6 • Results Published – The Journal of Clinical & Aesthetic Dermatology

13. Indication - ***The LunulaLaser device is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.)***
    - June 3rd, 2016 • FDA Market Clearance K153164
    - Device-Erchonia Lunula Laser • Results Published - Journal of Clinical and Aesthetic Dermatolgy

14. Indication - ***The ZERONA Z6 OTC Laser is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference.***
    - December 16th, 2016 • FDA Market Clearance K162578
    - Device-Erchonia Zerona Z6 OTC • Results Will Not be Published

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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 • FDA Market Clearance K180197
    - Device-Erchonia FX 635 • Results Published eMedical Research & Journal of Pain & Relief

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 –***
    a. 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,
    b. 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
    - Device – Red/Violet multi-diode • Results Published Medical Devices: Evidence and Research

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 • FDA Market Clearance K211186
    - Device – Red multi-diode • Results Submitted to be Published

20. Indication **– *Erchonia FX-405 Laser is indicated for relief of nociceptive musculoskeletal pain.***
    - November 12th, 2021 • FDA Market Clearance K212595
    - Device – Red/Violet multi-diode • Results Will Not be Published

21. Indication – ***Erchonia GVL –***
    a. while using the green and violet diode simultaneously, for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin,
    b. and while using the violet diode, to treat dermatological conditions, and specifically indicated to treat moderate inflammatory Acne Vulgaris
    - September 1st, 2022 • FDA Market Clearance K221987
    - Device – Green/Violet multi-diode • Results Will be Published