

## Erchonia FDA 510(k) Indications for Use *Updated 3/8/21*

1. Indication – ***Chronic neck and shoulder pain***
  - January 17<sup>th</sup>, 2002
  - Device – Red single diode
  - FDA Market Clearance K012580
  - 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<sup>th</sup>, 2004
  - Device – Red multi-diode
  - FDA Market Clearance K041139
  - 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 2<sup>nd</sup>, 2005
  - Device – Red/Violet multi-diode
  - FDA Market Clearance K050672
  - Results Will Not be Published
4. Indication – ***Breast Augmentation and Pain Associated with Surgery***
  - April 24<sup>th</sup>, 2008
  - Device – Multi-diode red
  - FDA Market Clearance K072206
  - Results Published - Breast Augmentation American Journal of Cosmetic Surgery
5. Indication – ***Non-Invasive Body Contouring and Fat Reduction***
  - August 28<sup>th</sup>, 2010
  - Device – Erchonia MLS Scanner (Zerona) (2009)
  - FDA Market Clearance K082609
  - Results Published - Lasers in Surgery and Medicine 41:799–809
6. Indication – ***Arm Circumference Reduction of the Upper Arms***
  - May 14<sup>th</sup>, 2012
  - Device – Erchonia MLS Scanner (Zerona)
  - FDA Market Clearance K121690
  - Results Published - Seminars in Cutaneous Medicine and Surgery
7. Indication – ***Reduction in the Appearance of Cellulite***
  - May 17<sup>th</sup>, 2013
  - Device – Erchonia Verju Laser System with Massager
  - FDA Market Clearance K130922
  - Results Published - Lasers in Surgery and Medicine
8. Indication – ***Non-invasive Body Contouring of the Waist, Hips and Thighs***
  - May 17<sup>th</sup>, 2013
  - Device – Erchonia Verju Laser System with Massager
  - FDA Market Clearance K130922
  - Results Published - American Journal of Cosmetic Surgery
9. Indication – ***Adjunct to Chronic Heel Pain Arising from Plantar Fasciitis***
  - April 14<sup>th</sup>, 2014
  - Device – Erchonia ALLAY (FX 635 Laser)
  - FDA Market Clearance - K132940
  - 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 21<sup>st</sup>, 2014
  - Device – Erchonia SHL (10 Head)
  - FDA Market Clearance K142042
  - 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 15<sup>th</sup>, 2015
  - Device – Zerona-Z6
  - FDA Market Clearance K143007
  - 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 21<sup>st</sup>, 2015
  - Device – Zerona-Z6
  - FDA Market Clearance K150446
  - 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 3<sup>rd</sup>, 2016
  - Device-Erchonia Lunula Laser
  - FDA Market Clearance K153164
  - Results Published - Journal of Clinical and Aesthetic Dermatology
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 16<sup>th</sup>, 2016
  - Device-Erchonia Zerona Z6 OTC
  - FDA Market Clearance K162578
  - 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 21<sup>st</sup>, 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 1<sup>st</sup>, 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 8<sup>th</sup>, 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/m<sup>2</sup>*
- September 13<sup>th</sup>, 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 12<sup>th</sup>, 2021 • FDA Market Clearance K212595
  - Device – Red/Violet multi-diode • Results Will Not be Published