

# World Leader in Low Level Laser

## **MILESTONES**

Pioneered Low Level Lasers as a viable medical device in the US and working with FDA representatives championed the development of a new category for Biostimulation devices – NHN.

Granted first FDA market clearance for a low level laser in USA, January 17, 2002

- a) Device Single Diode Red
- b) Indication Chronic neck and shoulder pain k012580

Granted a second FDA market clearance September 30, 2004

- a) Device Multi-Diode Red
- b) Indication -- Low Level Laser Assisted Liposuction and reduction of pain associated with Surgery k041139

Granted third FDA market clearance May 2, 2005

- a) Device Multi Diode Red/Violet Diodes
- b) Indication -- Dermatological conditions, Acne Vulgaris K050672

Granted fourth FDA market clearance March 1, 2007

- a) Device Iontophoresis/Galvanic Generator
- b) Indication Plantar/Palmer Hydrohyresis K062792

Granted fifth FDA market clearance April 24, 2008

- a) Device -- Multi-Diode Red
- b) Indication -- Breast Augmentation and pain associated with surgery. K072206

Body Contouring with Laser - Submitted for 510(k) 12/5/2008 - Approval and New Classification expected by March 1, 2009

Word Recognition -- Submitted for 510(k) 12/5/2008 - Approval Expected with 3 months

### **CLINICAL RESEARCH**

Chronic Neck and Shoulder Pain/Low Level Laser – 2000 -- Sponsor and Monitor, IRB approved, doubled blind, placebo controlled, mutli-site, clinical study

a) Used in support of 501(k) submission

Study 1 Abstract

Chronic Neck and Shoulder Pain/Low Level Laser – 2001 -- Sponsor and Monitor, IRB approved, doubled blind, placebo controlled, mutli-site, clinical study

a) Study results used to obtain FDA clearance

Study 2 Abstract

Carpal Tunnel Syndrome/Low Level Laser- 2004 -- Sponsor and Monitor, IRB approved, doubled blind, placebo controlled, mutli-site, clinical study

- a) IRB Approved
- b) Awaiting implementation

Breast Implantation/Low Level Laser – 2007 -- Sponsor and Monitor, IRB approved, doubled blind, placebo controlled, mutli-site, clinical study

a) Study results used to obtain FDA clearance

Hair Restoration/Low Level Laser – 2008 -- Sponsor and Monitor, IRB approved, doubled blind, placebo controlled, mutli-site, clinical study

- a) IRB Approved
- b) Awaiting implementation

Sponsor and Monitor, IRB approved, doubled blind, placebo controlled, mutli-site, clinical study – Burn Healing and Pain Reduction/Low Level Laser – 2005

- a) In development
- b) FDA final evaluation in process done waiting on grant money.

Sponsor and Monitor, double blind, placebo controlled, multi-site, clinical study – Low Back Pain -- 2008 a) Developing the study protocol

Body Contouring -Laser Scanner Waist Hip and Thighs-Pilot Study

- a) Conducted informal pilot 2006
- b) Finalizing FDA comments
- c) Clinical Trial started 11/2007

Word Recognition/Low Level Laser -- Sponsor and Monitor, IRB approved, double-blind, placebo controlled, multi-site, clinical study

- a) Obtained IRB approval
- b) Started in April 2007
- c) Study 30% complete
- d) Preliminary results -- 44% difference between Real and Placebo

Capsular Structure Study - James Baker, MD -- 2008

- a) Study protocol submitted for reveiw
- b) Awaiting IRB approval

Tinnitus/Low Level Laser -- Sponsor and Monitor, IRB approved, double-blind, placebo controlled, multisite, clinical study

- a) Obtained IRB Approval
- b) Started in April 2007
- c) Study in Progress

## PATENTS AND TRADEMARKS (by product line)

#### LASER

6,605,079 - Method For Performing Lipoplasty Using External Laser Radiation

a) US and PCT Countries

6,746,473 - Therapeutic Laser Device, Multi-diode

a) US and PCT Countries

6,013,096 - Hand held Laser Light Generator Device

a) US and PCT Countries

7,118,588 - Scanning Laser Treatment

a) US and PCT Countries

D500,361 - Combined Hand Held Medical and Therapuetic Treatment Device

Laseressence™

DermaLaser™

Laserologist™

LipoLaser™

Laserology™

Neira-4L®

**ProPerformance®** 

THL™

The Hair Laser™

Ortho-Laser™

3LT®

Lasersculpting™

LaserHear™

LaserAid™

Takes the Scar Out of Scar Tissue™

Zerona™

## **PERCUSSOR**

6,875,186 - Pressure Activated Percussive Actuated Device

6,599,260 - Chiropractic Percussor Apparatus With Compact Percussion-Applying Head Assembly

## **ADJUSTER**

6,602,211 - Chiropractic Adjustor Device

**6,537,236** - Chiropractic Adjustor Device, Housing Configured For Enhanced Heat Dissipation and Symmetrical Force

D460,190 - Chiropractic Adjustor Device

7,169,169 - Chiropractic Adjustor Device with Rotation Hub

# **EB / IONTOPHORESIS**

7,341,597 - Method and Device for Electrolytic Hydrotherapy

a) US and PCT Countries

ЕВ™

EBPro™

Energy Balance™

Energy Balancer™

#### **COMPANY**

Numerous Patents pending for:

- a) Device
- b) Application
- c) US
- d) PCT

E®

**Erchonia**®

The Healing Light®

World Leader in Low Level Laser Technology™

## UNIVERSITY RESEARCH

University of California - San Diego

- a) Flap Study 10/07 Completed
- b) Apoptosis 04/07- Completed
- c) Mitochondria / ATP- On going Completion in early 2008

Columbia University

a) Acne – Awaiting IRB Approval – To be complete 2008

University of Cincinnati

a) Muscle Strength - Clinical Trial on-going

### **PUBLICATIONS**

- Plastic and Deconstructive Surgery –Neira -- 2001
- AACS- Neira, Jackson, Dedo -- 2002, 2003, 2004, Pending review for 2007
- Clinics in Plastic Surgery -- Neira- 2006
- Aesthetic Plastic Surgery Neira 2003
- Journal of Clinical Laser Medicine and Surgery Al WatBan -- 2004

## **PRESENTATIONS**

## **BURNS**

- NABS UCSD, Nelson, Shanks 2002, 2003, 2004 2005, 2006, 2007
- ABA Nelson 2004
- Southwest Regional Nelson 2005
- John Bostwick International Meeting Nelson 2005

#### LIPO

- Plastic, Reconstructive and / or Cosmetic Surgery
  - ASPS Neira, Rameriz -- 2001
  - AACS Neira, Jackson, Dedo, Roche, Butterwick, Lim 2002, 2003, 2004, 2005, 2006, 2007
  - ASAPS Slattery 2003
  - ADD Slattery -- 2003
  - Mexican Plastic Surgery Society Rameriz 2003
  - CA Plastic Surgery Society Slattery 2002
  - World Congress on Liposuction Neira, Jackson, Dedo 2002, 2003, 2004, 2005, 2006, 2007

- ASLMS
  - Lipo Shanks Pain Shanks

# **WOUND HEALING**

• APTA – Chu, Klienkort – 2002, 2003