

# **Position Paper on Low Level Laser Therapy (LLLT)**

## **September 2004**

### **I. Purpose**

The purpose of this document is to review the available literature concerning the use of Low Level Laser Therapy (LLLT) for the treatment of a variety of musculoskeletal conditions including carpal tunnel syndrome. It is focused to the rationale, outcomes to date published in peer reviewed medical literature, indications, and positions taken by other payers in terms of the authorization for payment of this treatment. This information should assist MCOs and providers in authorization decisions for this service.

### **II. Background**

BWC has received several inquiries regarding the reimbursement of LLLT for the treatment of carpal tunnel syndrome (CTS). LLLT has been proposed as a treatment of CTS and other painful musculoskeletal disorders such as arthritis, epicondylitis, and myofascial pain syndromes. Low-level lasers refer to the used of red-beam or near-infrared lasers with a wavelength between 600-1000 nm and Watts from 5-500 milliwatts. When applied to the skin, these lasers produce no sensation and do not burn the skin. Because of the low absorption by human skin, it is hypothesized that the laser light can penetrate deeply into the tissues where it has a photobiostimulative effect. The exact mechanism of its effect on carpal tunnel syndrome and other soft tissue conditions is unknown. Hypotheses have included improved cellular repair and stimulation of the immune, lymphatic and vascular systems.

### **III. FDA Approval of MicroLight 830**

The MicroLight 830 Laser manufactured by the MicroLight Corporation of America has received clearance for marketing from the U.S. Food and Drug Administration (FDA) specifically for the treatment of carpal tunnel syndrome. The device is termed a "non-thermal laser capable of penetrating deep into tissue." The laser energy promotes the process of photobiostimulation which is theorized to produce "an increase in the cellular metabolism rate, which expedites cell repair and stimulation of the immune, lymphatic and vascular systems." The result is reported to be an "apparent reduction in pain, inflammation, edema, and an overall reduction in healing time."<sup>1</sup>

In the data submitted to the FDA as part of the FDA 510(k) approval process, the treatment consisted of application of the laser over the carpal tunnel three times a week for five weeks. The labeling states that the "MicroLight 830 Laser is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with carpal tunnel syndrome." Other protocols have used low-level laser energy applied to acupuncture points on the fingers and hand. This technique may be referred to as "laser acupuncture."

### MicroLight 830 Study

The following study was described in the application to the United States Food and Drug Administration by MicroLight Corporation of America requesting approval to market the MicroLight 830 Laser.

“In 1998 the MicroLight Corporation embarked on a double blind study for the use of low level lasers in the treatment of carpal tunnel syndrome. The study protocol targeted approximately 135 patients diagnosed with carpal tunnel syndrome with moderate to severe symptoms, with a mean Symptom Severity Scale score of at least 2.0, with a score of at least 30 on a 100 point VAS pain scale, who have failed conservative therapy for at least one month and who have not had previous carpal tunnel release surgery. One half of the study subjects received treatment with the active laser and one half received treatment with a placebo laser.

Patients were treated three times a week for five weeks. Follow up times were 1, 6, and 12 weeks after the last treatment, at which time information was recorded on each patient. Once the study was completed a statistical analysis was performed on the active and placebo groups.

Treatment was considered successful if a patient showed a 30% or more reduction in VAS pain score at the 12 week follow-up point. By this definition, the MicroLight laser successfully treated 55.8 % of the patients in the active group, compared to 40% success for patients in the placebo group. No adverse effects from the MicroLight 830 treatment were noted.

IMPROVEMENT	Percentage of Patients	
	MicroLight	Placebo
Any	75.6%	69.3%
30% or more	55.8%	40.0%
50% or more	45.3%	29.3%

No other information is available on this study. The demographics of the two study groups, other factors to consider, diagnostic criteria, or measurement of objective outcomes such as change in EMG are unknown. It does not appear this study was ever published in peer-reviewed literature.<sup>2</sup>

#### **IV. General Motors Study**

A randomized, double-blind, prospective study comparing the efficacy of physical therapy alone and physical therapy plus LLLT in the treatment of employees of General Motors on disability due to carpal tunnel syndrome was reported in January 1995. All participants were assigned to receive physical therapy and one group was administered LLLT three times per week for five weeks while the other group received sham LLLT.

Employees diagnosed with CTS were offered to participate in the study. Acceptance criteria included a clinical history consistent with CTS, a symptom complex of pain and burning or tingling (paresthesias) in the fingers and hand in the distribution of the median nerve, a positive Tinel's sign and Phalen's test, and abnormal baseline EMG. Of the 119 subjects who participated, half were randomly assigned to receive physical therapy plus LLLT and the other half received identical physical therapy plus sham LLLT. The physical therapy program was designed for the treatment of carpal tunnel syndrome. The therapist and treating individuals were blinded as to whether the individual received sham LLLT or actual LLLT. Duration of the program was five weeks.

Prior to starting the study, all participants received EMG, baseline studies of tactile sensitivity of the median nerve distribution using the Semmes Weinstein Monofilament test, grip and wrist strength measurements and torque measurements, and wrist blood flow measured non-invasively using the Metriflow AFM-100 blood flow scanner for magnetic resonance.

The LLLT was administered by trained individuals using the MicroLight 830 Laser System which uses a 830 nm wavelength to penetrate 3 to 5 cm of tissue. The mean system has three lasers with a mean power output of 90 mW which are timed to deliver a 33 sec treatment cycle. There is no perceived sensation at the skin with treatment such as a perception of heat, pain, or cold. Endpoints for the study included completion of five weeks of physical therapy or withdrawal from the study for any reason.

Outcome measurements performed at the conclusion of the study included sensory threshold, grip and pinch strength, wrist range of motion, upper extremity blood flow, median nerve EMG conduction and latencies, and return to work upon completion of the program.

Table 1 shows the Demographics of the participants in the study.

**Table 1**

**Demographic Characteristics of the Groups**

	<u>Group A – Active Laser</u>	<u>Group B- sham laser</u>
Mean Age $\pm$ sd	43.4 $\pm$ 9.0	43.7 $\pm$ 6.6
Male / Female	22/19	19/29
Hand Surgery	50%	63%

The functional assessment reported results are shown in Table 2. Changes are given as percent of pre-therapy baseline. A positive number indicates a functional improvement while a negative value indicates worsening.

Table 3 presents “a comparison of patients whose symptoms (and capabilities) improved during treatment versus those whose worsened. Both groups had a few subjects exhibiting no change on one or more measures, and these have been omitted from the analysis. Note that the average improvement among those showing improvement from Group B is notably larger than in Table 2, with smaller difference in the values for Group A. This is probably a result of a higher incidence of symptomatic worsening in Group B receiving physical therapy only. These negative changes would, therefore, reduce the mean benefit calculated for the group. Also note that the maximum improvement for the combined therapy group is substantially larger than the maximum improvement for the physical therapy only group (for those showing improvement).”

Table 4 shows the results of wrist blood flow comparing the pre to post-treatment values. The 119 participants had 132 wrists that met criteria. These individuals were grouped on basis of symptoms and whether prior surgery had been performed. Any differences in wrist blood flow failed to achieve statistical significance.

Table 5 shows the mean nerve conduction velocities of the subsets of the median nerve and segments of the nerve. “None of the active versus sham laser comparisons was statistically significant.”

The authors reported that there was a statistically significant difference in the percentage of the two groups working at 90 days post-treatment. They reported 72% of those receiving physical therapy plus LLLT had returned to work versus 41% of those who had received physical therapy and sham LLLT.

**Table 2**  
**Mean Percent Change In Function**

<b><u>Parameter</u></b>	<b><u>Group A</u></b> <b><u>Laser &amp; Phys. Ther.</u></b>	<b><u>Group B</u></b> <b><u>Physical Ther. Only</u></b>	<b><u>Statistical Signif.</u></b> <b><u>Grp. A vs. Grp B</u></b>
<b>Sensory Thresh</b>			
Median n., extend.	1.4%	2.0%	n.s.
Median n. flexed	2.8%	2.5%	n.s.
<b>Grip Strength</b>			
Flexion	48%	14%	p<0.01
Extension	41%	11%	p<0.01
Pinch	28%	15%	p<0.05
Peak Torque	17%	8%	n. s.
<b>Wrist Torque</b>			
Flexion-60 o/s	30%	36%	n.s.
180o/s	5%	48%	n.s.
Extension – 60 o/s	12.8%	25%	n.s.
180o/s	-3.6%	10%	n.s.
<b>Wrist Work</b>			
Velocity =60o/s	30.5%	48%	n.s.
Velocity =180o/s	26.7%	20%	n.s.
<b>Range of Motion</b>			
Flexion	14.1%	1.3%	n.s.
Extension	11.7%	5%	n.s.
Radial Dev.	31.2%	-2.9%	p<0.01
Return to Work	72%	41%	p<0.05

**Table 3**  
**Comparison of Functional Measures –**  
**Improved Function versus Deteriorated Function**  
**(Distribution and Average Change)**

	<u>Group</u>	<u>%</u>	<u>Avg. Change</u>	<u>Ranges</u>	<u>%</u>	<u>Avg. Changes</u>	<u>Range</u>
Flex Grip	A	87	47%	3-543%	13	11%	2-30%
	B	72	26%	3-85%	28	19%	2-55%
Ext. Grip	A	79	50%	1-334%	21	22%	4-39%
	B	68	25%	1-145%	32	16%	2-60%
Pinch Grip	A	76	52%	4-300%	24	25%	3-97%
	B	67	42%	5-200%	33	29%	7-91%
Grip Torque	A	65	38%	1-225%	35	19%	4-100%
	B	68	31%	1-110%	32	16%	1-61%

**Table 4**  
**Wrist Blood Flow (ml/min/100 cc tissue)**  
**Mean Values by Group, Pre- and Post-treatment**

<u>Diagnosis</u>	<u>n</u>	<u>Laser</u>	<u>Pre-treatment</u>	<u>Post-Treatment</u>
Asymptomatic	56	Active	2.67	2.78
		Sham	2.72	2.73
Symptomatic	59	Active	2.63	2.72
		Sham	2.31	2.34
Symptomatic	73	Active	2.52	2.92
		Sham	2.76	3.06

**Table 5**  
**Mean Nerve Conduction Latencies**  
**Pre- and Post-treatment**  
**Mean Value (+/- Std. Dev.)**

<u>Nerve/Site Tested</u>	<u># of Wrists</u>	<u>Laser</u>	<u>Pre-Treatment</u>	<u>Post-Treatment</u>
Motor	27	Active	55.54 (3.1)	56.45 (2.9)
	27	Sham	56.28 (4.3)	56.89 (2.6)
Sensory	25	Active	55.79 (2.7)	67.15 (4.1)
	28	Sham	2.37 (.32)*	58.12 (2.6)
Palmar	11	Active	2.33 (.2)	2.16 (.27)
	11	Sham	2.37 (.37)	2.15 (.21)**
Wrist Motor	27	Active	4.77 (.70)	4.33 (.81)***
	37	Sham	4.54 (.67)	4.39 (.57)
Wrist Sensory	27	Active	3.97 (.56)	3.85 (.64)
	32	Sham	3.93 (.61)	3.89 (.51)

\*actual reported value

\*\*Significant treatment effect  $p < 0.05$

\*\*\*Significant treatment effect  $p < 0.05$

The authors concluded that the functional measurement of grip strength was positively affected by both the physical therapy program and the combined program of physical therapy and laser treatment. The improvement in grip strength was significantly greater in the group which received laser treatment. The sensory thresholds were not significantly improved during the 5-week treatment period for either group. Other than radial deviation, wrist range of motion was not affected. EMG results were inconclusive with the only significant improvement was in the active laser group when measuring motor nerve latency across the wrist. The sham group showed improvement in the palmar sensory latency. Wrist blood flow at the wrist failed to show significant increase. Return to work was reported as 72% for those treated with LLLT versus 41% for those treated with sham LLLT.<sup>3</sup>

This study apparently was not published in a peer-reviewed journal. There are several concerns with the study. Despite being reported as random allocation, the demographics show the treatment group to have 22 of 41 participants to be male whereas only 19 of 48 in the sham group were male. Fifty percent of the treatment group had had surgery and 63% of the sham treatment group had had surgery. These differences were not addressed by the authors. There was no mention of the comparison of male versus female or surgical versus non-surgical patients in terms of improvement of hand strength. There is no mention of the duration of symptoms or diagnosis. There is no discussion on return to work as to whether the individual returned to the same job or alternative job, other confounding variables such as diabetes or age, or duration of symptoms or surgical intervention.

## V. Other Published Studies

A double-blind, randomized study of the effect of LLLT in CTS was performed by Irvine et. al.<sup>4</sup> Inclusion criteria included symptoms and findings of CTS supported by electrophysiological evidence of CTS resulting primarily in conduction slowing or conduction block of the sensory and motor nerve fibers. Excluded from the study were those individuals with axonal loss, patients with arthritic diseases, trauma to the wrist or arm, and previous carpal tunnel surgery. Outcome measures included symptom assessment using the Levine Carpal Tunnel Syndrome Questionnaire, hand function performance using the Purdue pegboard test, and electrodiagnosical testing. Participants were randomly assigned to receive active LLLT or sham LLLT. The active LLLT was an 860 nm wavelength laser emitting a 60-mW beam with an intensity of 3 J/cm<sup>2</sup> per second over an area of 0.01 cm<sup>2</sup> for a total dose of 6 J/cm<sup>2</sup> in 15 seconds. Twenty sites over and around the carpal tunnel were treated. The sham probe was identical except it did not have an active laser. Each subject received identical type treatments three times per week for five weeks. Fifteen patients agreed to participate in the study. Eight were randomly assigned to the treatment group and seven to the sham group. There were no significant differences in the two groups. After completion of treatment, there was no significant difference in the Levine CTS Questionnaire scores though both groups had significant improvement in their scores when measured four weeks post completion of treatment. The hand function as assessed by the Purdue pegboard test also showed no significant change. The authors concluded that “LLLT is no more effective in improving CTS symptoms or median nerve and hand functions than is placebo”.

A randomized, double-blind, cross-over study was performed by Naeser et. al.<sup>5</sup> to determine whether real or sham LLLT plus microamperes transcutaneous electric nerve stimulation applied to acupuncture points significantly reduces pain in carpal tunnel syndrome. The study population consisted of eleven patients who met electrodiagnostic study criteria which included having a median nerve sensory peak latency that was  $\geq 3.6$  m/s with median nerve motor latency  $\leq 4.3$  m/s (borderline/mild CTS) or median nerve sensory peak latency  $\geq 3.6$  m/s and the median nerve motor latency was  $> 4.3$  m/s (moderate CTS). Excluded were individuals with evidence of denervation. In addition, individuals were required to have at least 2 other signs or symptoms of CTS: paresthesias in the median nerve distribution, a positive Phalen sign at 60 seconds, a positive Tinel's sign, nocturnal awakening, hypoesthesia, and wrist and hand pain. Participants were randomly assigned to receive 9 to 12 sessions of active or sham LLLT and microamperes TENS treatment. Neither treatment caused sensations (pain, temperature, tingling) and participants were blinded as to whether they received actual versus sham treatment. Primary outcome measure was the pain score from the McGill Pain Questionnaire. Secondary measures included measures of median nerve sensory peak latency, motor latency, Phalen sign, and Tinel Sign. Of the 11 participants, three (27%) were considered “placebo responders”. Seven of the remaining eight participants had the reported pain scores reduced by more than 50% post active LLLT plus microamps TENS treatment. They also were noted to have reduction in the mean sensory latency post active treatment, but there was no change in the mean motor latency. All eleven reported resumed their previous work activities with less or no pain. They have remained stable at 1 to 3 years.

There are several studies reported by the manufacturers of the lasers and, abstracts or small case series, and websites available. In general these do not have control groups,

describe methodology, and outcome measures beyond three months. Most of these documents are not published in peer-reviewed journals.<sup>6</sup>

## **VI. Use of LLLT in Other Conditions**

LLLT has been tried in numerous other conditions including arthritis, epicondylitis, chronic neck pain, chronic back pain, and wound healing. Most studies have included case reports or series, reported as abstracts or websites, and rarely published in peer-reviewed literature. Since the primary outcome reported is improvement of symptoms or pain, it is important that a control or placebo group be included in any scientific study.

Basford et. al. performed a randomized, controlled trial of LLLT for the treatment of lateral epicondylitis.<sup>7</sup> Inclusion criteria included symptoms of more than 30 days duration, normal neurological examination with tenderness of the lateral forearm and lateral epicondyle. Examination also included measurement of grip and pinch strength and resisted wrist and second finger extension. Excluded were workers' compensation and litigation cases, individual with prior surgery, or those who received cortisone injections in the previous 30 days. Participants were randomized to receive either active or sham laser treatments. Treatments consisted of irradiation for 60 seconds at 7 sites along the forearm located above, at, and just below the lateral epicondyle, the distal wrist extensor tendons, the volar wrist, and two sites on the medial epicondyle three times per week for four weeks. Irradiation was performed with a 1.06  $\mu\text{m}$  Nd:YAG CW laser. Average intensity was 204  $\text{mW}/\text{cm}^2$ . Follow-up assessments were performed at one month after the last session. Fifty two individuals entered the study and 47 completed the study. Twenty-three were in the active group and 24 in the sham or control group. The groups did not differ significantly in terms of activity, symptom duration, medication usage, gender, or age. On final evaluation, there were no statistically significant differences between the treatment and sham groups in terms of pain, tenderness to palpation, grip strength, or pinch strength. Strength differences were significant between baseline and end of treatment for resisted wrist extension and at follow-up evaluation for resisted long finger extension, but treated subjects were somewhat weaker and more painful than the controls. The authors concluded that LLLT is not effective in treating lateral epicondylitis.

A metaanalysis was performed by Brosseau<sup>8</sup> in 1999 of all reported randomized clinical trials using LLLT to treat rheumatoid arthritis and osteoarthritis. Using the methodology of the Cochrane Collaboration, only 13 articles met the inclusion criteria. Pooled data indicated that LLLT when used to treat patients with rheumatoid arthritis reduced pain by 70% in comparison to placebo and reduced morning stiffness. There were no differences in functional assessment, range of motion, and local swelling. For osteoarthritis, the results were conflicting in the different studies and no significant improvement could be identified. Among the factors for future studies the authors recommended special attention to low versus high dose LLLT, wavelength, nerve versus joint application, and treatment duration.

In 2004, Brosseau performed another metaanalysis reviewing clinical trials using LLLT to treat osteoarthritis. Seven trials met inclusion criteria. LLLT was used to treat pain in 184 patients and 161 received sham LLLT. The authors concluded that the results for improvement of pain were conflicting and no firm conclusions could be drawn. The stated "The lack of significant effect for OA (osteoarthritis) pain relief may be related to the paucity of data, heterogeneous methods of LLLT application, heterogeneous data that cannot be combined and poor quality of the trials conducted to date."<sup>9</sup>

## VII. Authorization/Coverage Position of Other Payors

A review of the literature from other payors resulted in inadequate evidence to support the medical effectiveness of LLLT for the treatment of CTS. This included the following positions:

- The Regence Group (Washington) Medical Policy , Medicine Section - Low Level Laser Treatment of Neuromuscular Pain Disorders, Policy No. 105, Revised/Effective Date: 01/06/2004.

“Low level laser treatment is considered investigational for all indications, including, but not limited to carpal tunnel syndrome and other pain disorders”

- Aetna: Clinical Policy Bulletins, Number 0363, Subject: Cold Laser Therapy

Aetna considers cold laser therapy experimental and investigational because there is inadequate evidence of the effectiveness of low-energy (cold) lasers in wound healing, pain relief, or for other indications such as musculoskeletal dysfunction, arthritis, and neurological dysfunctions.

“Although the results from large, uncontrolled, open trials of low-energy lasers in inducing wound healing have shown benefit, controlled trials have shown little or no benefit. The analgesic effects of low-energy lasers have been most intensely studied in rheumatoid arthritis. Recent well-designed, controlled studies have found no benefit from low energy lasers in relieving pain in rheumatoid arthritis or other musculoskeletal conditions. Furthermore, although positive effects were found in some earlier studies, it was not clear that the pain relief achieved was large enough to have either clinical significance or to replace conventional therapies.

Recently published systematic reviews of the evidence have concluded that there is a lack of adequate evidence of effectiveness of cold laser therapy for treatment of chronic wounds (e.g., Schneider and Hailey, 1999; Cullum et al, 2002; Flemming and Cullum, 2002), musculoskeletal disorders (de Bie et al, 1998), arthritis (Brosseau et al, 2002a; Brosseau et al., 2002b; Marks and de Palma, 1999; Puett and Griffin, 1994), tuberculosis (Vlassov, et al., 2002), tinnitus (Waddell & Canter, 2002), and pain (Crawford et al, 2002; Gross et al, 2002; van der Heijden et al, 2002; Binder, 2002; Crawford, 2002; Speed and Hazleman, 2002). Recently reviews have also concluded that low-energy laser therapy (e.g., Microlight 830, Microlight Corporation of America, Missouri City, TX) is ineffective in treating carpal tunnel syndrome (Gerritsen et al, 2002; O'connor et al, 2003).

- *ODG: Official Disability Guidelines-Treatment in Workers' Compensation Integrated Treatment/Disability Duration Guidelines “Carpal Tunnel Syndrome”:*
  - Not recommended. A recent RCT concluded that LLLT is no more effective in the reduction of symptoms of CTS than is sham treatment. [Irvine 2004/8](#)
  - Another very small study concluded that low-level laser therapy (LLLT) plus microamperes transcutaneous electric nerve stimulation (TENS) applied to

acupuncture points reduced pain in carpal tunnel syndrome, but until larger studies are performed, this procedure should be considered investigational.

[Naeser](#)

- (PhotoThera, Carlsbad, CA, has received FDA clearance for the Acculaser Pro™, a medical device that has been designed for the temporary relief of hand and wrist pain associated with carpal tunnel syndrome. As of March 2004, PhotoThera has received 510(k) clearance for adjunctive use in providing temporary relief of pain associated with Iliotibial Band Syndrome (ITBS).”<sup>10</sup>

## VIII. Coding and Billing Information

There is no specific CPT code identifying LLLT. HCPC code S8948 specifically identifies LLLT. BWC does not accept “S” codes.

Other codes that are documented for possible use depending upon provider types include:

<u>CPT Code</u>	<u>Description of CPT</u>
97026	Application of a modality to one or more areas; infrared
97039	Unlisted physical medicine/rehabilitation modality
97780	Acupuncture, one or more needles; without electrical stimulation
97781	Acupuncture, one or more needles, with electrical stimulation
97799	Unlisted physical medicine/rehabilitation service or procedure
98940	Chiropractic manipulative treatment (CMT); spinal, one or two regions
98941	CMT; spinal three or four regions
98942	CMT; spinal five regions
98943	CMT; other than the spine, one or more regions
S8948 (HCPCS)	Application of a modality (requiring constant provider attendance) to one or more areas: low level laser, each 15 minutes.

Source: The Regence Group

Most studies to date have used four to five weeks of treatment with three treatments per week.

According to a manufacturer’s website dealing with low level lasers, the most frequently used billing code has been 97039 which is billed 15 minute per unit. “The use of this code is recommended based on policies determined in response to inquiries to various local insurance entities throughout the country and Workers’ Compensation Commission Guidelines.”<sup>11</sup>

The estimated total reimbursements for treatment would be \$1000 to \$1500.

## IX. Recommendation

Preliminary reports of LLLT to treat carpal tunnel syndrome and other musculoskeletal disorders have been positive but randomized controlled trials have not demonstrated effectiveness of the treatment except in one study by Naeser with only 11 participants.

All authors have noted that additional studies should be performed. No one has published any population outcome studies as to whether LLLT provides a resolution of symptoms so that individuals do not in the future require surgical intervention. There are still multiple factors that have not been addressed including the appropriate type of laser and wave length of the laser, duration or amount of power to be delivered, and number of treatments. While the FDA has approved the marketing of the device, many payers have declined to provide recognize LLLT as effective treatment.

When considering authorization of payment of LLLT for treatment of individuals through BWC, the Ohio Supreme Court in the Miller Decision has ruled that consideration must be given as to whether the requested treatment is reasonably related to the allowed conditions, whether the services are reasonably necessary for treating the allowed conditions, and whether the cost of the service is medically reasonable. In view of the above information, it appears that LLLT is still considered experimental and investigational at best. Results of treatment have not been consistent so that it is difficult to state that such treatment would be necessary. Last, given the reported number of visits required to be nine to 12 visits, the cost of such treatment would be approximately \$1000 to \$1500. These costs appear to be somewhat unreasonable for a treatment that has not been demonstrated in the medical literature to be effective.

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<sup>1</sup> “ML 830™ Laser” @<http://www.microlightcorp.com/ml830.asp> verified June 13, 2003.

<sup>2</sup> U. S. Food and Drug Administration: “510(k) Summary as required by Section 807.92(c)” @ <http://www.fda.gov/cdrf/pdf/k010175.pdf> verified September 2, 2004.

<sup>3</sup> “General Motors Study” @<http://www.sportlaser.com/doubleBlind.html> verified June 16, 2003.

<sup>4</sup> Irvine J, Chong SL, et. al.: “Double-Blind Randomized Controlled Trial of Low-Level Laser Therapy in Carpal Tunnel Syndrome” Muscle & Nerve 30:182-187, 2004.

<sup>5</sup> Naesar MA, Hahn KAK, Lieberman BE, and Branco KF: “Carpal Tunnel Syndrome Pain Treated with Low-Level Laser and Microamperes Transcutaneous Electric Nerve Stimulation: A Controlled Study” Archives of Physical Medicine and Rehabilitation 83:978-988, 2002.

<sup>6</sup> Rogers, P: “Low Level Laser Therapy [LLLTT]: A Bibliography of recent Papers” @<http://users.med.auth.gr/~karanik/English/articles/laser.html> verified June 13, 2003.

<sup>7</sup> Basford JR, Sheffield CG, and Cieslak KR: “Laser Therapy: A Randomized, Controlled Trial of the Effects of Low Intensity Nd:YAG Laser Irradiation on Lateral Epicondylitis” Archives of Physical Medicine and Rehabilitation 81:1504-1510, 2000.

<sup>8</sup> Brosseau L, Welch V, et. al.: “Low Level Laser Therapy for Osteoarthritis and Rheumatoid Arthritis: A Metaanalysis” Journal of Rheumatology 27:1961-1969, 2000.

<sup>9</sup> Brosseau L, Welch V, et. al.: “Low Level Laser Therapy (Classes I, II, and III for Treating Osteoarthritis (Cochrane Review)” in *The Cochrane Library*, Issue 3, 2004.

<sup>10</sup> “Carpal Tunnel Syndrome” *Official Disability Guidelines - Treatment in Workers’ Compensation* @<http://www.odg-twc.com> verified September 7, 2004.

<sup>11</sup> “Billing Codes” @<http://www.laserhealing.net/codes.html> verified June 13, 2004.