

## Clearance and Approvals for AVACEN Medical Device

We want to share some exciting information with all of you... below you will find the “FDA Clearance and E.U. CE Mark Approval and Health Canada Approval” for our medical device, the AVACEN 100.

The information below should help you understand why people are getting such amazing results! While this is the case, please keep in mind the importance of remaining compliant with our claims in promoting and marketing the AVACEN. As a reminder, here’s our disclaimer (what we are “allowed” to claim according to the FDA, Health Canada & E.U.)

**U.S. FDA Clearance:** The AVACEN is a non-invasive FDA Cleared Class II medical device as a heat therapy system indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains; muscular relaxation; and the temporary increase in “head to toe” overall microcirculation.

**E.U. CE Mark Approval and Health Canada Approval:** A heat therapy system indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains; the temporary relief of widespread pain associated with fibromyalgia; muscular relaxation; and the temporary increase of microcirculation.

**IMPORTANT:** The AVACEN is not for sale in the U.S. for any non-cleared or non-approved indications. It is suggested that you contact a doctor before using the AVACEN if you are under 18 years of age.

Other important points about the AVACEN:

- 17 patents (5 U.S. & 12 International)... with more patents pending
- Recipient of the 2017 “Frost & Sullivan” New Product Innovation Award (E.U. Over The Counter Fibromyalgia Pain Management device)
- Over 25 million plus safe treatments with zero adverse events reported since 2009.

Currently we have completed many studies for Autism, Heart Disease, Fibromyalgia, Type II Diabetes, Diabetic Wound Healing, Planter Fasciitis, etc. We have submitted to the FDA for Clearance for Fibromyalgia. We look forward to additional studies on Autism, Type II Diabetes, etc. Our goal is to continue growing our list of “allowable” claims with clinical studies submitted to the FDA. We have submitted 9 new studies to the FDA in the last 3 years.

**Kevin Humphrey (626) 755-3176 KevinLHumphrey@gmail.com**  
**Herriman, Utah**