

SUMMARY OF CLINICAL & PRECLINICAL TRIALS

Clinical Trials

Year	End Point	Title	Institution	Primary Investigators	N	Journal /Publication	Outcome
2022	Tissue Oxygen (TCPO2) and Peripheral Blood Flow	Randomized Placebo-Controlled Clinical Trial of Gloves and Stockings Made from Infrared-Emitting Fabric (CELLIANT®) for Transcutaneous Oxygen and Peripheral Blood Flow in Diabetic Patients with Vascular Impairment	Loyola University Chicago	Dr. Lawrence A. Lavery, Dr. Michael R. Hamblin and Kathryn Davis	20	Journal of Textile Science & Engineering	Initial findings suggest evidence of improvement in peripheral blood flow of diabetic patients
2021	Wrist and Elbow Pain	Effect of CELLIANT® Armbands on Grip Strength in Grip Strength in Subjects with Chronic Wrist and Elbow Pain	Long Beach VA Memorial Hospital	Dr. Ian Gordon and Dr. Michael R Hamblin	70	Research Journal of Textile and Apparel	Improved grip strength
2019	Grip Strength	Effect of Shirts with 42% CELLIANT® Fiber on tcPO2 Levels and Grip Strength in Healthy Subjects: A Placebo-Controlled Clinical Trial	Long Beach VA Memorial Hospital	Dr. Ian Gordon, Dr. Mark Vangel and Dr. Michael R Hamblin	24	Journal of Textile Science and Engineering	Improved grip strength of over 12% in the dominant hand after 90 minutes
2018	Tissue Oxygen (TCPO2)	Randomized Controlled Trial Comparing the Effects of Far-Infrared Emitting Ceramic Fabric Shirts and Control Polyester Shirts on Transcutaneous PO2	Long Beach VA Memorial Hospital	Dr. Ian Gordon, James Wason, Dr. Lawrence Lavery, Dr. Michael R Hamblin and MS Thein	153	Journal of Textile Science and Engineering	Average increase in TCPO2 of 8.4% after 90 minutes for 71% of the subjects
2012	Tissue Oxygen (TCPO2)	The Test Report on the Impacts of Subject Socks with the Application of CELLIANT® Technical Fibers on Transcutaneous Oxygen Pressure on a Man's Foot	Academy of Chinese Sciences	Dr. Li Shaojing, Wu Chuanhong, Gao Jian, Zhu Li and Wen Liwei	100	N/A	Increase in TCPO2 across all healthy subjects
2012	Tissue Oxygen (TCPO2)	Transcutaneous Partial Pressure of Oxygen (tcPO2) as a Primary Endpoint to Assess the Efficacy of CELLIANT® as a Vasoactive Material	Long Beach VA Memorial Hospital	Dr. Ian Gordon and Dr. Michael Coyle	51	N/A	An average increase of 7% in TCPO2
2011	Performance & Recovery	Apparel with Far Infrared Radiation for Decreasing an Athlete's Oxygen Consumption During Submaximal Exercise	University of Calgary	Dr. Jay Worobets, Dr. Darren Stefanyshyn and Emma Skolnik	12	Research Journal of Textile and Apparel	Elite/club cyclists VO2 reduced by 1.1%, increasing anaerobic threshold
2010	Sleep (pilot)	Double Blind, Placebo Controlled, Crossover Trial on the Effect of Optically Modified Polyethylene Terephthalate Fiber Mattress Covers on Sleep Disturbances in Patients with Chronic Back Pain	University of CA Irvine	Dr. Marcel Hungs and Dr. Annabel Wang	6	N/A	Nighttime awakenings, sleep quality and sleep efficiency improved
2009	Foot Pain	Effect of Optically Modified Polyethylene Terephthalate Fiber Socks on Chronic Foot Pain	University of CA Irvine	Dr. Ian Gordon and Dr. Robyn York	55	BioMed Central Complementary & Alternative Medicine	Statistically significant reduction of pain and improved comfort for subjects (diabetic/foot neuropathy)
2005	Tissue Oxygen (TCPO2)	Holofiber Study of Thirteen (13) Healthy Subjects	University of Texas A&M	Dr. Graham McClue	13	N/A	An average increase in TCPO2 levels from 10% to 24%
2003	Tissue Oxygen (TCPO2)	Improving Blood Flow with Holofiber in the Hands and Feet of High-Risk Diabetics	Loyola University Chicago	Dr. Lawrence Lavery	20	N/A	An average increase in TCPO2 levels from 12% in the hands and 8% in the feet of diabetic subjects

Preclinical Trial

Year	End Point	Title	Institution	Primary Investigator	Journal /Publication	Outcome
2021	Anti-inflammatory Markers and Improved Motion	CELLIANT® Bedding Moderates Autoimmune and Inflammatory Responses	University of Belgrade	Dr. Jasmina Djuretić, Dr. Mirjana Dimitrijević, Dr. Marija Stojanović, Dr. Jelena Kotur Stevuljević, Dr. Michael R Hamblin, Dr. Ana Micov, Dr. Radica Stepanović-Petrović and Dr. Gordana Leposavić	Scientific Reports	The appearance of the symptoms of collagen type II induced arthritis was postponed, while the disease was milder in infrared radiation exposed rats compared to non-exposed rats. Objective biochemical measurements of cytokines and autoimmunity were improved.

As part of the 513(g) submission process, the FDA reviewed and commented on appropriate health and wellness claims for CELLIANT products.

The FDA has determined that CELLIANT® products are medical devices as defined in section 201 (h) of the Federal Food, Drug and Cosmetic Act and are general wellness products.

The FDA determined products containing CELLIANT® are medical devices because they are intended to temporarily increase blood flow and local circulation at the site of application in healthy individuals.

The FDA has not approved or designated CELLIANT® products for any purpose and has not made any determination about, or endorsement of, its stated use or benefits.





SUMMARY OF TECHNICAL & PHYSICAL TRIALS

Year	End Point	Title	Institution	Primary Investigators	Journal /Publication	Outcome
2017	Solar IR Emissivity	Infrared Radiative Properties and Thermal Modeling of Ceramic-Embedded Textile Fabrics	Exponent	Dr. David Anderson, John Fessler, Matthew Pooley, Scott Seidel, Dr. Michael R Hamblin, Haskell Beckham and Dr. James F Brennan	Biomedical Optics Express	Emissivity increased by approximately 10x when sunlight is also used to power Celliant technology
2016	IR Emissivity	Engineered Emissivity of Textile Fabrics by the Inclusion of Ceramic Particles	Exponent	Dr. David M. Anderson, Matthew Pooley, Haskell W. Beckham and Dr. James F Brennan	Optics Express	Emissivity increased by .14 MW per CM2 at fabric temperature of 32 Celsius with a 42% Celliant fabric vs. control
2012	Principals of IR	Far Infrared Radiation (FIR)- Its Biological Effects and Medical Applications	Harvard/Wellman Center for Photomedicine	Dr. Michael R Hamblin and Dr. Fatma Vatansever	Photonics and Lasers in Medicine	Far Infrared Radiation (FIR) its biological effects and medical applications

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CELLIANT® is designated as a Class 1 Medical Device in Australia, Canada, the European Union, Japan, New Zealand, the United Arab Emirates and the United Kingdom. CELLIANT® is cleared to market in China, India, Indonesia, Korea, Malaysia, Mexico, Peru, Philippines, Saudi Arabia, Singapore, South Africa, Taiwan, Thailand and Vietnam, with more countries and regions to follow.

