

FDA Chooses ThermoTek to Participate in its Opioid Innovation Challenge!

FLOWER MOUND, TX - As part of the FDA’s ongoing commitment to address the opioid crisis, the FDA’s Center for Devices and Radiological Health (CDRH) launched Innovation Challenge in May 2018. This effort resulted in ThermoTek being chosen by the FDA as one of only eight out of more than 250 applications to participate in the Opioid Innovation Challenge.

In ThermoTek’s proposal, we described the novelty of the VascuTherm, the development plan for the VascuTherm; the anticipated benefit of the VascuTherm when used by patients; and, the impact on public health as compared to other available alternatives.



As part of the FDA’s Innovation Challenge, ThermoTek’s VascuTherm is being evaluated as the only thermal/compression device within the Innovation Challenge intended to treat opioid use disorder or treat pain.

“We believe this effort will provide improved awareness of the benefits of the therapies provided by ThermoTek’s VascuTherm devices. There is still a lot of work to be done in this effort, but we hope that through working with the FDA we can expand the VascuTherm’s recognized indications for use; which will result in broader acceptance and better insurance coverage.” said Sam McSpadden, CEO of ThermoTek.



According to the CDC, almost 218,000 Americans died from overdoses related to prescription opioids from 1999 to 2017. The VascuTherm is a safe, non-narcotic, non-invasive and non-addictive alternative to Rx opioids!

Throughout the Breakthrough Device designation process with the FDA, ThermoTek will work to ensure that patient safety is our number one priority and we’ll still be held to the FDA’s gold standard of safety and effectiveness.