



Re: Anodyne® Therapy FDA Regulatory Clearance

Dear Customer:

The Anodyne device was cleared for marketing in March of 1994 under a 510(k) by the FDA under the name SpectroPad (#K931261) for temporarily increasing local circulation and reducing pain. The clearance letter was issued to the technology founder's company, which was called SMI at the time. The device was later renamed and transferred to Anodyne Therapy, LLC. The FDA was notified of the change to the device name and the manufacturer. Pursuant to applicable regulations, no additional regulatory submission was required and no change in the device name or the manufacturer was noted in the FDA database. Hence, Anodyne information still appears in the FDA database under Spectropad (#K931261), where it is classified as an infrared lamp (ILY). A copy of the current listing on the FDA database is included for your reference.

It is important to note that most noninvasive medical devices like Anodyne are registered with the FDA under the 510(k) process. This process examines safety and limits the marketing claims that can be made by the manufacturer. It does not limit the clinical applications for which the device can be used by health care professionals. Use by healthcare professionals is limited by applicable clinical practice acts and the exercise of sound clinical judgement. In this connection, infrared has been widely used by health care professionals as an adjunctive modality to increase circulation, reduce pain, stiffness and muscle spasm. Examples of some medically appropriate uses are contained in various physical medicine and rehabilitation guidelines issued by insurance carriers.

Please call me at 800-521-6664 x 110 if you have further questions.

Sincerely,

Craig Turtzo

Craig Turtzo
Chief Executive Officer

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