

Devices & Diagnostics Letter

May 24, 2010 | Vol. 37 No. 21

Medispec Told to Submit 510(k) or PMA for Its Class I Device

After getting a warning letter for not getting a 510(k) or PMA for its Class I device, Medispec immediately informed the FDA that no changes had been made to the Radialspec that would require clearance or approval.

When Medispec submitted a registration notification to market the radial wave therapy device a few years ago, the FDA determined it was a Class I, Rhona Shanker, a consultant for Medispec, told *D&DL*. The FDA has exempted most Class I devices from the 510(k) process.

But after reviewing the Israeli company's website, which includes information about the Radialspec, the FDA sent a warning letter March 12 claiming Medispec had not notified the agency of its intent to market the device in the U.S. and it lacked the required marketing approval. The FDA posted the letter last week.

Since responding to the letter, Medispec said it has heard nothing from the agency. Meanwhile, the company's website continues to provide information about the Radialspec, noting that it is an FDA Class I device for treatment of orthopedic conditions in podiatry, physiotherapy, sports medicine and rehabilitation.

The warning letter is available at www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm211763.htm. — Mari Serebrov

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