

FDA Reclassifies Acupuncture Needles

DISPOSABLE ACUPUNCTURE NEEDLES, ONCE DEEMED "INVESTIGATIONAL," NOW DECLARED SAFE AND EFFECTIVE

Editorial Staff

The status of acupuncture needles in the United States has always been somewhat tenuous. In 1973, the Food and Drug Administration classified acupuncture needles as "experimental" and "investigational." This meant that if someone wanted to use acupuncture needles, it could only be as part of a research study with written protocols; further, every person participating in a study involving acupuncture had to be advised in writing that acupuncture needles were experimental.

Acupuncturists across the country have almost uniformly ignored these legal requirements and have therefore placed themselves at risk whenever malpractice actions are brought. A patient could claim that malpractice had occurred simply because they had not received the appropriate disclosures and warnings relating to the fact that acupuncture needles were investigational and experimental. Much of this has now changed. The FDA has now reclassified disposable acupuncture needles from Class III investigational devices to Class II devices. Class II devices are those devices that the FDA is satisfied are safe and effective.

There are some important limitations on this reclassification:

- This reclassification only covers disposable needles. It does not apply to reusable acupuncture needles. "If someone wanted to obtain reclassification of reusable needles, they would need to submit a 501(K) application and document how reusable needles would not constitute an additional risk of infection," explained Ms. Melpomeni Jeffires, reclassification coordinator for the FDA.
- The reclassification of disposable acupuncture needles does not constitute a decision by the FDA as to whether or not the practice of acupuncture is safe and effective. The FDA does not have jurisdiction over the health care professions, only the devices used on patients.

"This reclassification will substantially reduce the potential malpractice exposure of acupuncturists from claims that acupuncture needles are inherently unsafe," noted Michael Schroeder, vice president and general council of the American Acupuncture Council, the largest malpractice insurance carrier in the country for acupuncturists. He added: "This is only part of the battle, however, because we still need to obtain the same reclassification for reusable needles."

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