

## Endotec Case Sheds Light, But Not Enough, On Custom Devices, Says Attorney

A Florida judge's recent ruling in *U.S. v. Endotec* highlights the need for FDA guidance on regulation of custom devices, according to a leading expert on custom device law.

"Imperious silence is not a proper role for FDA to take when so many people in the device industry care about this topic. It is good that [the Endotec] case forced them out to talk about it," Robert J. Klepinski, an attorney with Fredrikson & Byron's Minneapolis office, told "The Gray Sheet" in an interview.

Klepinski has written numerous articles on FDA device regulation and compliance, including a 2006 *Food & Drug Law Journal* article on the custom device provisions in the Food, Drug and Cosmetic Act.

"What we need from FDA is some guidance to go through the good guidance system so they can express publicly what they contend their position is on custom devices."

In 2004 Klepinski proposed to FDA a draft guidance on custom devices. FDA has had internal discussions about providing more guidance on custom devices, but these have yet to bear fruit ("The Gray Sheet" Oct. 21, 2002, p. 23).

### Endotec 2, FDA 1

In October 2006 FDA sued orthopedics device maker Endotec, alleging that the Florida company was distributing a total ankle replacement system, a total knee replacement system and a temporomandibular joint (TMJ) replacement system without FDA approval.

The company argued that the devices could be legally sold without a PMA or 510(k) because they were "custom devices" as defined by the Medical Device Amendments to the Food, Drug and Cosmetic Act.

The act states a device is exempt from premarket clearance and approval requirements if it is not generally available on the market or to other physicians, is made in a specific form for a specific patient or specific physician, and must "necessarily deviate" from otherwise applicable FDA requirements to meet that specific need.

During the trial, the government argued that Endotec's *Buechel-Pappas* ankles were not custom devices because although each ankle device was

tailored and sized for a specific patient, the design of each implant did not necessarily deviate from devices that are generally available.

The government's lawyers cited the 1985 case of *Contact Lens Manufacturers Association v. FDA*, in which a D.C. circuit court ruled that contact lenses could not be considered custom devices just because individual lenses are created for specific patients' prescriptions.

However, in an order released April 30, Judge G. Kendall Sharp of the U.S. District Court for the Middle District of Florida agreed with Endotec that unlike contact lenses, the B-P ankles are not "merely a variation" within a range of sizes because they were each made to order with particular features to accommodate a specific patient.

Because custom devices are unique, they cannot be studied in the type of large clinical trial usually required for a PMA approval or determined to be substantially equivalent to a predicate device for a 510(k).

During the trial, FDA officials testified that the impossibility of bringing a custom device through the PMA or 510(k) process is one of the main justifications for including the custom device exemptions in the law. But, FDA had granted Endotec an investigational device exemption for the B-P knee, suggesting the device could be studied in a clinical trial, an FDA official testified.

Despite Endotec's IDE for the B-P ankle, the judge concluded that "each ankle is sufficiently unique that clinical investigations would be impractical."

Judge Sharp ruled that the B-P ankles are custom devices, but warned Endotec against any unlawful advertising or marketing of the devices.

In the same trial, the government charged that Endotec sold an "adulterated" device when it manufactured a special *Hemi TMJ* implant for a cancer patient who was missing a large piece of bone in her jaw. The judge agreed with the company that the device was custom, and therefore not subject to FDA approval, because it was unique and unlike the *Hoffman-Pappas* TMJ devices the company was studying in an IDE trial.

However, in the same April 30 order, Judge Sharp ruled against Endotec on the charge that it

distributed modified *Buechel-Pappas* knee devices without appropriate approval.

The company argued that the devices are custom because the addition of a *FlexGlide Bearing with Anterior Stop* and a *Fenning Modular Bearing* are allowable variations of the 2002 510(k) for the B-P knee.

But the judge observed that the company was unable to identify any special need of the patient that necessitated these modifications to the cleared device. Judge Sharp also concluded that the B-P knee with the Fenning Modular Bearing is significantly different than the cleared version of the B-P knee because the bearing is a two-piece metal and polyethylene component, while the original is a one-piece polyethylene component.

### Case Provides Some Guidance

Device manufacturers will study Kendall's ruling for guidance on how to interpret the custom device rules since FDA has not provided guidance on custom devices, Klepinski said, but the case still leaves some questions unanswered.

"On the most difficult call, as to what changes it takes for it to be custom for a particular patient, I'm not sure this case clarifies it," Klepinski said.

"It puts one opinion down on where the line should be drawn. I'm not sure it's the right one, but it gives more clarity than the FDA ever has on that particular point. So the judge has done us a tremendous favor just laying out the issues and forcing people to think about providing clear guidance boundary areas for customs."

Klepinski said FDA has contributed to confusion in the industry about the exact definition of custom devices because it has yet to issue any regulations or guidance on it. "FDA has chosen by policy to ignore this part of the statute. They keep saying that custom devices are 'rare,' but whenever they say [that], they're not relying on the statute and they're not relying on the legislative history," Klepinski said.

"It's an internal [FDA] policy to potentially ignore this part of the law and pretend it doesn't exist. It's like little children putting their hands on their ears and saying, 'Rare! Rare! Rare!' and trying to ignore the fact that it can happen."

— Reed Miller ([re.miller@elsevier.com](mailto:re.miller@elsevier.com))

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