Successful Class II Medical Device Preemption Decision

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We don't see many successful applications of preemption with respect to 510k, Class II medical devices since Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), so when we do, it's a big deal. Here's one. Today, in Degelmann v. Advanced Medical Optics, Inc., No. 10-15222, slip op. (9th Cir. Sept. 28, 2011), the Ninth Circuit held that a claim that a contact lens solution manufacturer should have tested its product against a particular microorganism was preempted.

Here's the reasoning, in a nutshell. (1) there can be "specific requirements," even in 510k, Class II cases; (2) an FDA guidance document (significantly, not a formal regulation) allowed contact lens solutions to come to market under 510k provided the manufacturer did certain specific things; (3) one of those things was the "primary performance criteria" of a "stand alone procedure" - that the solution "show[] the prescribed level of efficacy in killing five representative microorganisms"; (4) the defendant's solution undisputably met this test in wiping out the five specified bugs; (5) plaintiff's claim demanded that the solution also kill a different microorganism that was not on the FDA's list; (6) since plaintiff's demand related to a different microorganism, it was "different from" and "in addition to" the FDA's device specific requirement; (7) all claims "different from" or "in addition to" a device specific requirement" are expressly preempted. Degelman, slip op. at 18567-70.

So if you're a 510k, Class II device manufacturer, and the FDA's tagged your product with a device-specific guidance document, you may be able to assert preemption after all, at least against some claims.

Given the strength of the preemption defense, it's something worth looking into.