

**UNPUBLISHED**

**UNITED STATES COURT OF APPEALS**

**FOR THE FOURTH CIRCUIT**

COY W. SANDERS, SR.,

Plaintiff-Appellee.

v.

No. 95-1967

OPTICAL RADIATION CORPORATION,

Defendant-Appellant.

Appeal from the United States District Court  
for the District of South Carolina, at Columbia.  
Matthew J. Perry, Jr., Senior District Judge.  
(CA-94-2039-3)

Argued: December 4, 1995

Decided: July 30, 1996

Before WILKINSON, Chief Judge, RUSSELL, Circuit Judge, and  
THORNBURG, United States District Judge for the Western  
District of North Carolina, sitting by designation.

---

Affirmed in part, vacated and remanded in part by unpublished per  
curiam opinion.

---

**COUNSEL**

**ARGUED:** David Eidson Dukes, NELSON, MULLINS, RILEY &  
SCARBOROUGH, Columbia, South Carolina, for Appellant.  
Charles L. Henshaw, Jr., FURR & HENSHAW, Columbia, South  
Carolina, for Appellee. **ON BRIEF:** James F. Rogers, NELSON,  
MULLINS, RILEY & SCARBOROUGH, Columbia, South Carolina,  
for Appellant.

Unpublished opinions are not binding precedent in this circuit. See Local Rule 36(c).

---

## OPINION

### PER CURIAM:

This case concerns the extent to which the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, preempt state law causes of action for product liability. After oral argument in this appeal, the Supreme Court issued a decision in Medtronic, Inc. v. Lohr, 64 U.S.L.W. 4625 (U.S. June 26, 1996), which addresses the central issue in this case -- the reach of the MDA's preemption provision, 21 U.S.C. § 360k(a). Based on the Court's ruling in Lohr, we affirm in part and vacate and remand in part.

### I.

Appellant Optical Radiation Corporation (ORC) manufactures intraocular lenses, which are artificial eye lenses implanted in persons whose natural lenses have been removed in cataract surgery. The lenses are eligible for an Investigational Device Exemption (IDE) under FDA regulations, *see* 21 U.S.C. § 360j(g); 21 C.F.R. pt. 813, allowing them to be marketed on a limited basis without undergoing the rigorous FDA pre-market approval process, *see* 21 § U.S.C. 360e. ORC received an IDE for one type of its "Stableflex" lens in 1981, and for another type in 1982.

A Stableflex lens was implanted in appellee Coy W. Sanders, Sr.'s right eye in May 1986, and was removed in August 1991. Sanders asserts that he suffered corneal decompensation and decreased visual acuity as a consequence of several defects in the lens. He brought state law claims against ORC on July 14, 1994, alleging negligence, strict liability, lack of informed consent, breach of warranty, and negligence *per se*. The last cause of action, under South Carolina law, is a common law claim alleging violation of statutory standards, *see* Whitlaw v. Kroger, Co., 410 S.E.2d 251 (S.C. 1991), here FDA regu-

lations governing the use of intraocular lenses under an IDE, e.g., 21 C.F.R. §§ 813.27, 813.46, 813.153.

ORC moved for summary judgment, asserting that all of Sanders' state law claims were preempted by the MDA. The MDA prohibits states from "establish[ing] or continu[ing] in effect with respect to a device intended for human use any requirement" that is "different from, or in addition to, any requirement applicable under this chapter to the device" and that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." 21 U.S.C. § 360k(a). The district court denied ORC's summary judgment motion, finding that Sanders' claims survive the MDA's preemption provision. The court certified its order for interlocutory appeal.

## II.

We first take up Sanders' negligence per se action, because the Supreme Court directly addressed this sort of claim in Lohr. Sanders argues that, since his negligence per se claim incorporates federal standards, it cannot involve any requirement "different from, or in addition to" a federal requirement and so, as the district court found, cannot be preempted. Lohr supports this logic. The plurality found that "[n]othing in §360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." Lohr, 64 U.S.L.W. at 4632. The dissent agreed that state law "claims are not pre-empted by §360k to the extent that they seek damages for[a defendant's] alleged violation of federal requirements. Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is 'different from, or in addition to' requirements under federal law." Id. at 4637.

Thus, to the extent that Sanders' state law actions allege noncompliance with federal requirements, they are not preempted. By definition, his negligence per se claim falls in this category; others of his claims may as well, though it is somewhat difficult to divine from the pleadings. But to the extent that these other claims-- of strict liability, negligence, lack of informed consent, and breach of warranty --allege something other than noncompliance with federal standards,

Lohr suggests a case-specific assessment of the claims and of any applicable federal requirements: "The statute and regulations . . . require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope . . ." Id. at 4634. This sort of analysis should be undertaken by the district court in the first instance, guided by the Lohr decision. As a result, we vacate and remand the judgment of the district court regarding any of Sanders' claims that do not simply allege violation of federal standards.

III.

For the foregoing reasons, the judgment of the district court is

AFFIRMED IN PART, VACATED AND REMANDED IN PART.