MIMEDX Announces Favorable Federal Court Ruling in AXIOFILL® Regulatory Classification Matter

September 23, 2026

Court Vacates FDA Determinations That AXIOFILL Is Not Minimally Manipulated and Should Be Classified as a Biological Product

Order Further Holds That Minimal-Manipulation Analysis Must Consider Tissue Characteristics Relevant to Reconstruction, Repair or Replacement in the Recipient

MARIETTA, Ga., Sept. 23, 2026 (GLOBE NEWSWIRE) -- MiMedx Group, Inc. (Nasdaq: MDXG) ("MIMEDX" or the "Company") today announced that the U.S. District Court for the Northern District of Georgia issued a favorable ruling in the Company's litigation challenging the U.S. Food and Drug Administration's ("FDA") regulatory classification of AXIOFILL, the Company's human placental-derived extracellular matrix particulate product.

The Court vacated FDA's determination that AXIOFILL is not a Section 361 HCT/P because it is more than minimally manipulated and FDA's determination that AXIOFILL should be classified as a biological product rather than a medical device. The Court remanded both matters to FDA for further consideration consistent with its order.

"This ruling favorably addresses the central issues of this matter. We are pleased the Court found that the FDA erred in its interpretation of the minimal-manipulation regulation and that the agency did not adequately explain the reasoning behind its divergent classification of AXIOFILL compared with similar products available on the market," stated Joseph H. Capper, Chief Executive Officer of MIMEDX. "We continue to believe that AXIOFILL meets the requirements for classification as a Section 361 HCT/P, and we look forward to engaging constructively with FDA as it reconsiders the matter consistent with the Court's order. Since its launch in 2022, AXIOFILL has demonstrated an impeccable safety profile and has helped countless patients navigate the surgical healing process."

In addressing whether AXIOFILL qualifies as a Section 361 HCT/P, the Court held that FDA had incorrectly interpreted its minimal-manipulation regulation by focusing on the placental disc's function in the donor—specifically, its function as a selective barrier between the fetal and maternal circulatory systems. The Court concluded that the applicable regulation instead requires FDA to consider the original characteristics of the tissue that are relevant to its utility for reconstruction, repair or replacement in the recipient.

The Court also vacated FDA's determination that to the extent AXIOFILL is not a Section 361 HCT/P, it is a biological product rather than a device. The Court found that FDA had classified other commercially available human-derived particulate products, similar to AXIOFILL, as medical devices without adequately explaining why AXIOFILL should be treated differently. The Court concluded that FDA's classification of AXIOFILL as a biological product was "arbitrary and capricious" because the agency had not provided "a reasonable explanation or record of evidence" supporting this disparate treatment.

About MIMEDX
MIMEDX is a pioneer and leader focused on helping humans heal. With more than a decade and a half of helping clinicians manage chronic and other hard-to-heal wounds, MIMEDX provides a leading portfolio of products for applications in the wound care, burn, and surgical sectors of healthcare. The Company's vision is to be the leading global provider of healing solutions through relentless innovation to restore quality of life. For additional information, please visit www.mimedx.com.

Contact:
Matt Notarianni
Investor Relations
470-304-7291
mnotarianni@mimedx.com