



For Immediate Release
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**AcuFocus Receives Approvable Letter from the U.S. FDA for the
IC-8[®] Small Aperture Intraocular Lens**

IRVINE, Calif., December 7, 2021 — AcuFocus, Inc., a privately held ophthalmic medical device company, today announced receipt of an Approvable Letter from the U.S. Food and Drug Administration (FDA) for its IC-8[®] small aperture intraocular lens (IOL) for cataract patients.

The letter indicates the FDA has completed its review of the IC-8[®] IOL Premarket Approval (PMA) Application and determined that the PMA substantially meets the requirements of the Food Drug and Cosmetic Act, and the FDA believes it can approve the application following successful completion of the pre-approval inspections at the company's manufacturing facilities in the U.S. and internationally.

In March of 2020, the FDA announced foreign facility inspections would be postponed due to the COVID-19 pandemic.¹ As a result of the current environment, AcuFocus anticipated a delay in the pre-approval manufacturing inspections of its international manufacturing facility.

“We are thrilled to receive the approvable letter from the FDA ahead of our MDUFA date and we look forward to working with the FDA to successfully complete these customary pre-approval inspections,” said Al Waterhouse, president and chief executive officer for AcuFocus. “The AcuFocus team and our global partners have worked diligently to build a robust, quality management system to ensure that both the integrity of our supply chain and the quality of our devices are maintained.”

Commercialization of the IC-8[®] IOL in the U.S. will begin upon successful completion of the manufacturing facility inspections and receipt of an official approval order from the FDA, which the company estimates in Q2 2022.

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ABOUT ACUFOCUS

[AcuFocus, Inc.](#), is a privately held ophthalmic medical device company that delivers breakthrough small-aperture intraocular products to address diverse unmet needs and help patients achieve their best personal vision. The IC-8® IOL received CE mark in 2015 and is available in select markets in Europe, Argentina, Singapore, Australia and New Zealand. AcuFocus is based in Irvine, California. www.acufocus.com

References:

¹ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-focuses-safety-regulated-products-while-scaling-back-domestic>