Fluxion Registers South San Francisco Facility as Medical Device Establishment With FDA

The Associated Press

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct 15, 2012--Fluxion Biosciences, Inc. announced today that it has registered its South San Francisco facility as a medical device establishment with the U.S. Food and Drug Administration. The company plans to use this facility to manufacture and distribute its IsoFlux System for circulating tumor cell analysis, which will be launched in November.

“Circulating tumor cells hold tremendous potential to the medical community,” said Jeff Jensen, CEO. “We’re committed to bringing our IsoFlux System into the clinic while ensuring the equipment meets the high expectations of clinical laboratories.” The IsoFlux System is a benchtop instrument that utilizes a proprietary microfluidic technology to isolate rare cells with high efficiency. The sample gets processed under more controlled and uniform conditions than bulk separations. This contributes to increased cell capture efficiency, purity, and viability. Samples processed with the IsoFlux System are optimized for downstream molecular testing such as real-time PCR, next generation sequencing (NGS), and immunoassays. The technology has been validated by a premier group of biopharma, diagnostic, and research institutes as part of the company’s Early Access Program ahead of the broader commercial launch.

Registration with the FDA is a required step to manufacture In Vitro Diagnostic instrumentation and kits. The IsoFlux System will be listed as a Class I medical device for In Vitro Diagnostic use when it is released next month.

About Fluxion Biosciences Fluxion Biosciences provides cellular analysis tools for use in critical life science, drug discovery, and diagnostic applications. Fluxion’s proprietary microfluidic platform enables precise functional analysis of individual cells in a multiplexed format. Products include the BioFlux™ System for studying cellular interactions, the IonFlux™ System for high throughput patch clamp measurements, and the IsoFlux™ System for circulating tumor cells. Fluxion’s systems are designed to replace laborious and difficult assays by providing intuitive, easy-to-use instruments for cell-based analysis. For more information about Fluxion Biosciences, visit www.fluxionbio.com.

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