Freedom Meditech Submits 510 (k) Application with FDA for First Product

SAN DIEGO, CA (October 13, 2011) – Freedom Meditech, Inc., developer of non-invasive ophthalmic products for the detection of disease and management of patient health, today announced it has submitted a Premarket Notification 510(k) application with the U.S. Food and Drug administration (FDA) for the company's ClearPath DS-120™ Lens Fluorescence Biomicroscope.

The ClearPath DS-120 incorporates the use of proprietary fluorescence spectroscopy to identify patients with signs of degenerative changes in the lens of the eye. This information, along with other data collected in a routine health examination, can aid in the diagnosis of diseases that affect the structural properties of the lens and assist a clinician in evaluating both the potential risk of chronic systemic disease and the need to institute appropriate patient management plans.

“Submitting our 510(k) application for the ClearPath DS-120 represents a significant milestone achievement for the company and our shareholders,” said Craig Mirsch, Chairman and CEO of Freedom Meditech. “We look forward to working with the FDA in order to bring this important product to market.”

Freedom Meditech’s 510(k) submission for the ClearPath DS-120 included performance data from a clinical trial that was both approved for conduct by a third-party institutional review board and managed by an independent contract research organization. The company also obtained independent third-party reviews, reports and certifications for software validation and verification, eye safety optical radiation hazard analysis and electromagnetic safety, immunity and compatibility.

Simultaneous to working with the FDA for U.S. market clearance of the ClearPath DS-120, the company intends to pursue CE marking for the market and commercialization of the device in the European Union.

About Freedom Meditech

Freedom Meditech, Inc. is a medical device company focused on the commercialization of novel ophthalmic technologies for the detection of disease and management of patient health. The company’s ClearPath DS-120™ Lens Fluorescence Biomicroscope technology non-invasively scans blue light into the lens of the eye in less than ten (10) seconds and produces a result immediately at the point of care. The test is painless, requires no special preparation such as fasting, and produces no bio-hazardous waste or disposal cost. The ClearPath DS-120 is an investigational device not currently available for market or sale in the United States.

The company maintains research and development operations throughout California and Ohio with supporting corporate and engineering activities in San Diego, CA. For more information, visit www.freedom-meditech.com.