Food and Drug Administration, HHS

§ 866.6010 Tumor-associated antigen immunological test system.

(a) Identification. A tumor-associated antigen immunological test system is a device that consists of reagents used to simultaneously detect and identify a panel of mutations and variants in the CFTR gene. It is intended as an aid in confirmatory diagnostic testing of individuals with suspected cystic fibrosis (CF), carrier identification, and newborn screening. This device is not intended for stand-alone diagnostic purposes, prenatal diagnostic, pre-implantation, or population screening.

(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications (510(k)s) to FDA.” See §866.1(e) for the availability of this guidance document.