Spectron IR Medical Infrared Imaging System

FDA 510(k) Indications for Use

FDA 510(k) #K032471

Spectron IR is the exclusive manufacturer of the TyTron C-500 IR Clinical Infrared Imaging System. The following is the FDA Premarket Notification 510(k) which is applicable to this system.

Indications for use: The TyTron C-500 IR Clinical Infrared Imaging System is intended for adjunctive diagnostic screening for the detection of breast cancer and other uses such as: peripheral vascular disease, neuromusculoskeletal disorders, extracranial cerebral and facial vascular disease, thyroid gland abnormalities, and various other neoplastic, metabolic and inflammatory conditions. Use of the TyTron C-500 is not intended to be a sole diagnostic procedure for these diseases and conditions.