§ 884.1600 Transabdominal amnioscope (fetoscope) and accessories.

(a) Identification. A transabdominal amnioscope is a device designed to permit direct visual examination of the fetus by a telescopic system via abdominal entry. The device is used to ascertain fetal abnormalities, to obtain fetal blood samples, or to obtain fetal tissue. This generic type of device may include the following accessories: trocar and cannula, instruments used through an operating channel or through a separate cannula associated with the amnioscope, light source and cables, and component parts.

(b) Classification. Class III (premarket approval).

(c) Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before January 29, 1987 for any transabdominal amnioscope (fetoscope) and accessories that was in commercial distribution before May 28, 1976, or that has on or before January 29, 1987 been found to be substantially equivalent to a transabdominal amnioscope (fetoscope) and accessories that was in commercial distribution before May 28, 1976. Any other transabdominal amnioscope (fetoscope) and accessories shall have an approved PMA or a declared completed PDP in after 24 weeks gestation when used to assess fetal maturity.