life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction, or to monitor therapy;
(4) For assessing the risk of cardiovascular diseases;
(5) For use in diabetes management;
(6) For identifying or inferring the identity of a microorganism directly from clinical material;
(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;
(8) For noninvasive testing as defined in §812.3(k) of this chapter; and
(9) For near patient testing (point of care).

Subpart B—Obstetrical and Gynecological Diagnostic Devices
§ 884.1040 Viscometer for cervical mucus.
(a) Identification. A viscometer for cervical mucus is a device that is intended to measure the relative viscoelasticity of cervical mucus collected from a female patient. Measurements of relative viscoelasticity are intended for use as an adjunct in the clinical evaluation of a female with chronic infertility, to determine the time of ovulation and the penetrability of cervical mucus to motile sperm.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §884.9.

§ 884.1050 Endocervical aspirator.
(a) Identification. An endocervical aspirator is a device designed to remove tissue from the endocervix (mucous membrane lining the canal of the cervix of the uterus) by suction with a syringe, bulb and pipette, or catheter. This device is used to evaluate endocervical tissue to detect malignant and premalignant lesions.
(b) Classification. Class II (performance standards).

§ 884.1060 Endometrial aspirator.
(a) Identification. An endometrial aspirator is a device designed to remove materials from the endometrium (the mucosal lining of the uterus) by suction with a syringe, bulb and pipette, or catheter. This device is used to study endometrial cytology (cells).
(b) Classification. Class II. The special controls for this device are:
(1) FDA’s:
   (i) “Use of International Standard ISO 10993 ‘Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,’” and
   (ii) “510(k) Sterility Review Guidance of 2/12/90 (K90–1),”
(2) Labeling:
   (i) Indication: Only to evaluate the endometrium, and
   (ii) Contraindications: Pregnancy, history of uterine perforation, or a recent cesarean section, and
(3) The sampling component is covered within vagina.

§ 884.1100 Endometrial brush.
(a) Identification. An endometrial brush is a device designed to remove samples of the endometrium (the mucosal lining of the uterus) by brushing its surface. This device is used to study endometrial cytology (cells).
(b) Classification. Class II. The special controls for this device are:
(1) FDA’s:
   (i) “Use of International Standard ISO 10993 ‘Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,’” and
   (ii) “510(k) Sterility Review Guidance of 2/12/90 (K90–1),”
(2) Labeling:
   (i) Indication: Only to evaluate the endometrium, and
   (ii) Contraindications: Pregnancy, history of uterine perforation, or a recent cesarean section, and
(3) The sampling component is covered within vagina.
§ 884.1560 Fetal blood sampler.

(a) Identification. A fetal blood sampler is a device used to obtain fetal blood transcervically through an endoscope by puncturing the fetal skin with a short blade and drawing blood into a...