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).

§ 884.1050 Endometrial aspirator.
(a) Identification. An endometrial aspirator is a device designed to remove samples of 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 (performance standards).

§ 884.1100 Endometrial brush.
(a) Identification. An endometrial brush is a device designed to remove tissue from the endocervix (mucous membrane lining the canal of the cervix of the uterus) by brushing 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).