§ 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 (performance standards).

§ 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:
   (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) Design and testing:
   (i) The sampling component is covered within the vagina, and
   (ii) For adherence of the bristles and brush head.