ATTACHMENT 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

SUPPLEMENTAL DATA SHEET

FORM APPROVED: OMB NO. 0910-0138
EXPIRATION DATE: January 31, 2003
(See OMB Statement on Page 2)

Panel Recommendation

1. GENERIC TYPE OF DEVICE
Human Papillomavirus (HPV) DNA Polymerase Reaction (PCR) Detection Device

2. ADVISORY PANEL

3. IS DEVICE AN IMPLANT (21 CFR 860.3)?
☐ Yes ☒ No

4. INDICATIONS FOR USE IN THE DEVICE'S LABELING

1. To screen patients with ASCUS (atypical squamous cells of undermined significance) Pap smear results and to provide materials suitable for HPV genotyping by direct automated DNA sequencing to determine the need for referral to colposcopy. The results of this test are not intended to prevent women from proceeding to colposocpy.

2. In women 30 years and older the HPV DNA Nest PCR Test™ in conjunction with genotyping by direct automated DNA sequencing can be used with Pap to adjunctively screen to assess the presence or absence of high-risk HPV types. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management.

5. IDENTIFICATION OF ANY RISKS TO HEALTH PRESENTED BY DEVICE

General No known risks to health presented by device are identified when used according to instructions.

6. RECOMMENDED ADVISORY PANEL CLASSIFICATION ANDPRIORITY

Classification _____ Priority (Class II or III Only) _____

7. IF DEVICE IS AN IMPLANT, OR IS LIFE-SUSTAINING OR LIFE-SUPPORTING AND HAS BEEN CLASSIFIED INA CATEGORY OTHER THAN CLASS III, EXPLAIN FULLY, THE REASONS FOR THE LOWER CLASSIFICATION WITH SUPPORTING DOCUMENTATION AND DATA

8. SUMMARY OF INFORMATION, INCLUDING CLINICAL EXPERIENCE OR JUDGMENT, UPON WHICH CLASSIFICATION RECOMMENDATION IS BASED

9. IDENTIFICATION OF ANY NEEDED RESTRICTIONS ON THE USE OF THE DEVICE *(e.g., special labeling, banning, or prescription use)*

10. IF DEVICE IS RECOMMENEDED FOR CLASS I, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM

Justification / Comments

☐ a. Registration / Device Listing _____

☐ b. Premarket Notification _____

☐ c. Records and Reports _____

☐ d. Good Manufacturing Practice _____

11. IF DEVICE IS RECOMMENDED FOR CLASS II, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM PREMARKET NOTIFICATION

☐ a. Exempt

☐ b. Not Exempt

Justifications/Comments

12. EXISTING STANDARDS APPLICABLE TO THE DEVICE, DEVICE SUBASSEMBLIES *(Components)* OR DEVICE MATERIALS *(Parts and Accessories)*

13. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs (HFZ-215)
1350 Piccard Drive
Rockville, MD 20850

OMB STATEMENT

Public reporting burden for this collection of information is estimated to average 1-2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration, (HFZ-215)
2094 Gaither Road
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to , a collection of information unless it displays a currently valid OMB control number.

INSTRUCTIONS FOR SUPPLEMENTAL DATA SHEET

1. The Supplemental Data Sheet should be prepared in conjunction with the General Device Questionnaire. The preparer should refer to Title 21 Part 860 of the Code of Federal Regulations for classification / reclassification definitions and procedures.

2. The Supplemental Data Sheet is designed to provide the device description, intended use, the risks of the device, the recommended class and the scientific support for the class and proposed level of controls.

3. The information requested by questions 1 through 8 must be provided for all devices.
4. Question 9 can be answered by referring to question 11 of the General Device Questionnaire.

5. Question 10 refers only to devices recommended for class I, and is a recommendation for exemptions form the General Controls listed.

6. Question 11 refers only to devices recommended for Class II.

7. Question 12 requests the listing of any existing standards for the device being classified. The standards to be listed could be standards drafted by professional groups, standards groups or manufacturers.

8. Send this completed form and the appropriate questionnaire to the address indicated in item 13.