



Panel Recommendation

1. GENERIC TYPE OF DEVICE
Osmotic Cervical Dilator

2. ADVISORY PANEL
85 Obstetrics and Gynecology

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

4. INDICATIONS FOR USE IN THE DEVICE'S LABELING

Dilation or ripening of the cervix uteri for the following procedures: 1) Hysteroscopy: If dilation is necessary, to permit the introduction of a hysteroscope through the cervix uteri. 2) Termination of pregnancy up to 24 weeks gestation period.

5. IDENTIFICATION OF ANY RISKS TO HEALTH PRESENTED BY DEVICE

General A clinical literature review has been conducted and confirms that undesirable side-effects of the device have been clinically evaluated and the device meet their requirements concerning characteristics and performance under normal conditions of use. In addition, there have been no MDRs filed for the product code LOB since Lamichel was introduced into the US market in 1983.

6. RECOMMENDED ADVISORY PANEL CLASSIFICATION AND PRIORITY

Classification Class II

Priority (Class II or III Only) High

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

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

A literature review of published material on synthetic cervical dilators showed no increased risk in using synthetic dilators versus natural Class II dilators.

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

Sale restricted to by or on the order of a physician. Intended for single patient use.

10. IF DEVICE IS RECOMMENDED 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*)

21 CFR 820 Quality System Regulations

ISO 13485:2003 Quality Systems-Medical Devices- Particular Requirements for the application of ISO9001

EN 552- Irradiation Processing Services

ANSI/AAMI/ISO 1137:1994 - Sterilization of Health Care Products. Requirements for Validation and Routine Control-Radiation Sterilization.

USP Biocompatibility (Product was tested prior to the issuance of ISO/EN 10993-1 and the FDA G-95 guidance on biocompatibility.)

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

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Food and Drug Administration, (HFZ-215)
2094 Gaither Road
Rockville, MD 20850

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