510(k) Summary

Submitted by:	Depalt Inc. 5013 Stonewick Court Plano, Tx 75093
Contact Person:	Rajeev Patel MD FACEP Chairman/CEO
Date Prepared:	September 20, 2007
Proprietary Name:	Depalt Vaginal Speculum 2000 Series and Depalt Lighting System
Common Name:	Speculum, Vaginal, Nonmetal
Predicate Device:	Kleenspec Single Use Vaginal Speculum and 790 series Cordless Illumination System by Welch Allyn, Inc. K070964 (510k number) Dynarex Vaginal Speculum by Dynarex Corporation K052314 (510k number) Bionix Reddy Lite listed with FDA on 12/30/1996. Device Class 1. Product Code: KYT
Description:	Depalt Vaginal Speculum is a nonmetal, single use (disposable) medical device used to expose the interior of the vagina. The vaginal speculum may be used with or without the Depalt Lighting System. Depalt Lighting System provides the light necessary to illuminate during procedures and examinations.
Intended Use:	Depalt Vaginal Speculum is used for the purposes of visualization and exposure of the interior of the vagina by a medical professional during gynecological and obstetrical procedures/examinations. Depalt Lighting System provides the light necessary to illuminate the field during procedures/examinations.
Material Used:	The Depalt Vaginal Speculum is constructed of Polystyrene.

JAN 22 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JAN 22 2008

Mr. Rajeev J. Patel
Chairman/CEO
Depalt, Inc.
5013 Stonewick Court
PLANO TX 75093

Re: K072762
Trade/Device Name: Depalt Vaginal Speculum and Depalt Lighting System
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HIB
Dated: December 10, 2007
Received: December 14, 2007

Dear Mr. Patel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K072762

Device Name: Depalt Vaginal Speculum and Depalt Lighting System

Indication For Use: Depalt Vaginal Speculum is used for the purposes of visualization and exposure of the interior of the vagina by a medical professional during gynecological and obstetrical procedures/examinations.

Depalt Lighting System provides the light necessary to illuminate the field during procedures/examinations.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)