K012203

AUG 2 7 2001

510(k) Summary

I. General Information on Submitter

Name:	Clay-Park Labs, Inc.
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Contact Person:	Candis Edwards
Date Prepared:	July 11, 2001

II. General Information on Device

Name: Clay-Park Labs Lubricating Jelly

Classification Name: Patient Lubricant

III. Predicate Device

K-Y® Lubricating Jelly

IV. Description of Device

The device is a water-based personal lubricant containing chlorhexidine gluconate and methylparaben as preservatives in a vehicle of glucono delta lactone, glycerin, hydroxyethylcellulose, sodium hydroxide, and purified water.

V. Intended Use

The Clay-Park Labs Lubricating Jelly is intended for personal lubrication when vaginal dryness causes discomfort and as a lubricant for insertion of rectal thermometers, enemas, douches, and similar types of nozzles.

VI. Technological Characteristics of Device Compared to Predicate Device

The technological characteristics of the Clay-Park Labs Lubricating Jelly are identical to those of the predicate device.

VII. Summary of Performance Data

Stability of the Clay-Park Labs Lubricating Jelly was confirmed throughout its labeled shelf-life (36 months) by a 36 month long-term stability study and a preservative effectiveness test in accordance with USP method <51>.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FEB 24 2014

Clay-Park Labs, Inc.
% Mr. Gary L. Yingling, Esq.
Kirkpatrick & Lockhart LLP
1800 Massachusetts Avenue, NW
Second Floor
WASHINGTON DC 20036-1221

Re: K012203
Trade/Device Name: Clay-Park Labs Lubricating Jelly
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated (Date on orig SE ltr): July 12, 2001
Received (Date on orig SE ltr): July 13, 2001

Dear Mr. Yingling:

This letter corrects our substantially equivalent letter of August 27, 2001.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K012203

Device Name: Clay-Park Labs Lubricating Jelly

Indications for Use:

The Clay-Park Labs Lubricating Jelly is indicated for personal lubrication when vaginal dryness causes discomfort and as a lubricant for insertion of rectal thermometers, enemas, douches, and similar types of nozzles.

PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IN NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The Counter Use ✓
(Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012203