K012203

AUG 2 7 2001

510(k) Summary

I. General Information on Submitter

Name:	Clay-Park Labs, Inc.
Address:	1700 Bathgate Ave. Bronx, NY 10457
Telephone:	(718) 960-9976
Fax:	(718) 960-0111
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
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 7 2001

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

Re: K012203
Clay-Park Labs Lubricating Jelly
Dated: July 12, 2001
Received: July 13, 2001
Regulatory Class: I
21 CFR §880.6375/Procode: 85 MMS

Dear Mr. Yingling:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4,xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

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