



HOSPICON PRODUCTS  
PHARMACEUTICAL SUPPLIES TO HOSPITALS

K970581

P102

EXHIBIT 7

SEP - 3 1997

CLINIJEL

510(K) NOTIFICATION SUMMARY & SE COMPARISON

We submit this 510(K) application in the belief that Clinijel would be considered substantially equivalent to:

H R Lubricating Jelly  
Triad Lubricating Jelly (K871169)  
K-Y Jelly

because (1) all four products make similar intended use statements, (2) Clinijel and K-Y Jelly use Hydroxyethylcellulose as a gelling agent while H R Lubricating Jelly and Triad Lubricating Jelly contain Hydroxypropyl Methylcellulose, which is similar in use to Hydroxyethylcellulose. A small additional quantity of Carbomer 934P in H R Lubricating Jelly and Triad Lubricating Jelly may be to facilitate sterilisation in sachet form. See Triad's 510(K) notification submission K871169, which claimed SE with H R Lubricating Jelly in sachet form, and (3) all of them target the same population.

Other comparative features may be seen in the SE Comparison table on the next page.

CLINIJEJL

SE COMPARISON

EXHIBIT 7

K-~~1~~ JELLY

	CLINIEJL	H R LUBRICATING JELLY*	TRIAD LUB JELLY	<del>K-1</del> JELLY
APPEARANCE	water white clear jelly	water white clear jelly	Not known	water white clear jelly
GELLING AGENT	Hydroxyethyl-cellulose	Hydroxypropyl Methyl-cellulose, Carbomer 934P	Hydroxypropyl Methylcellulose, Carbomer 934P	Hydroxyethylcellulose
PRESERVATIVES	Methylparaben & Propylparaben	Methylparaben & Propylparaben	Methylparaben & Propylparaben	Methylparaben
PROPYLENE GLYCOL/ GLYCEROL	Propylene Glycol	Propylene Glycol	Propylene Glycol	Glycerin
pH ADJUSTMENT WITH	Sodium Hydroxide	Sodium Hydroxide	Sodium Hydroxide	Sodium Hydroxide
CONTAINER	Aluminium-lined tube	Aluminium-lined tube	Aluminium-lined sachet	Aluminium-lined tube
SHELF LIFE	Up to 5 years	5 years	Not known	3 years

\*We understand that H R Lubricating Jelly was marketed prior to May 1976.

A method to prepare a jelly using H R Lubricating Jelly's ingredients is described on page 740 of Extra Pharmacopoeia Martindale, 25 th edition (19679).

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p2072



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP - 3 1997

Mr. Sadguru Y. Gaitonde  
Hospicon Products  
67 Compton Road  
London N21 3NU  
UNITED KINGDOM

Re: K970581  
Clinijel Lubricating Jelly  
Dated: July 18, 1997  
Received: July 28, 1997  
Regulatory class: II  
21 CFR §884.5300/Product code: 85 HIS

Dear Mr. Gaitonde:

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 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 requirement, 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K970581

Device Name: Clinijel lubricating jelly

Indications For Use:

Clinijel is specially formulated to provide vaginal moisture, lubricate condoms, and help ease insertion of tampons, rectal thermometers, enaema and douche nozzles.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Sathling  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K970581

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)