K040353

MAR 1 1 2004

SSL Americas, Inc.

Office of Regulatory Affairs
3585 Engineering Drive, Suite 200
Norcross, GA 30092-9214
Tel: 770-582-2222
Fax: 770-582-2204



# SSL Americas Premarket approval [510(k)] Summary

## Section II Summary

### II.A Submitter Information

SSL Americas
3585 Engineering Dr.
Suite 200
Norcross, GA 30092-9214
Phone: 770 – 582 – 2222
Fax: 770 – 582 – 2233
Contact person: Chris Robinson,
Date of Summary: February 2, 2004

### II.B General Device Information

Device Trade Name: Flight Sock
Device Common Name: Medical Support Stocking
Classification: General Hospital and Personal Use Therapeutic Devices

### II.C Predicate Devices

Venes Anti Embolism Stockings (K830696)
Jobst Travel Sock (K032325)

### II.D Device Description

SSL's Medical Support Stocking is a compression stocking in the 14 – 17mmHg range. It is composed of Polyamide / Elastane. A cotton feel Flight sock using air jet textured spun nylon.

### II.E Intended Use

SSL America's flight socks are intended to help prevent edema and leg discomfort and help prevent deep vein thrombosis for long distance travellers.

### II.F Substantial Equivalence

SSL America's flight socks are substantially equivalent in compression, purpose and composition to Futuro's Venes Anti Embolism Stockings (K830696) and Jobst Travel Sock (K032325). SSL conducted equivalency testing against Futuro's stocking and found SSL's sock to be equivalent in composition and compression.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2004

Ms. Kathleen J. Harris
Regulatory Manager
SSL Americas
3585 Engineering Drive
Suite 200
Norcross, Georgia 30092-9214

Re: K040353
Trade/Device Name: Medical Support Stockings (Flight Sock
Regulation Number: 880.5780
Regulation Name: Medical Support Stocking
Regulatory Class: II
Product Code: DWL
Dated: February 2, 2004
Received: February12, 2004

Dear Ms. Harris:

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 (PMA), 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 Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040353

# Indications for Use

510(k) Number (if known): ————————

Device Name: Medical Support Stockings (brand name Flight Sock).

Indications For Use: Help prevent edema and leg discomfort and help prevent deep vein thrombosis for long distance travelers. Over the Counter

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Irene Nouveau, Interim Branch Chief
(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices



510(k) Number: K040353