DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 9 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. George K.C. Chen
President and CEO
Skylark Device Company Limited
12th Floor, 34 Section 3
Chung Shan North Road Taipei
Taiwan ROC

Re: K983964
      Trade Name: Batch #6060 Conductive Gel
      Regulatory Class: II
      Product Code: IKC
      Dated: November 2, 1998
      Received: November 6, 1998

Dear Mr. Chen:

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) 594-4659. 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,
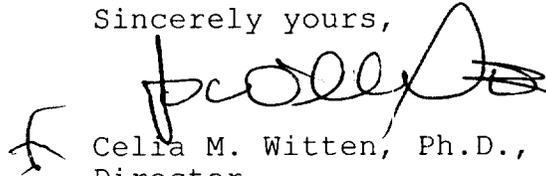
Celia M. Witten, Ph.D., M.D.
Director
Division of General and
    Restorative Devices
Office of Device Evaluation
Center for Devices and
    Radiological Health

Enclosure

510(k) Number (if known): _K98 3964_

BATCH #6060   CONDUCTIVE   GEL

:vice Name:_____

Indications For Use:

**FOR USE WITH TENS (TRANSCUTANEOUS ELECTRICAL NERVE
STIMULATORS) AND EMS (ELECTRICAL MUSCLE STIMULATORS).
CONDUCTIVE GEL IS USED WITH EXTERNAL ELECTRODES TO REDUCE
THE IMPEDACE OF THE CONTACT BETWEEN THE ELECTRODE SURFACE
AND THE SKIN.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(signature)
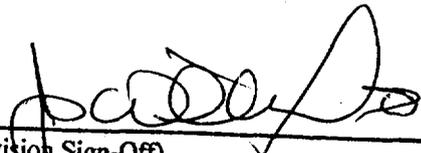
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number_____ _K983964_

Prescription Use_____   OR   Over-The-Counter Use _X_
  `er 21 CFR 801.109)