DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 1997

Mr. James S. Sanders
Sales Manager
Opportunity, Inc.
1200 Old Skokie Road
Highland Park, Illinois 60035-3028

Re: K971088, K971089, K971090, K971091, K971093, K971095
Trade Names: Opportunity Incision and Drainage Tray
Opportunity Laceration Tray
Opportunity Dressing Change Tray
Opportunity Tracheostomy Care Kit
Opportunity I.V. Start Kit
Opportunity Suture Removal Kit
Regulatory Class: K971088 (Unclassified)
K971089 (II)
K971090 (Unclassified)
K971091 (Unclassified)
K971093 (Unclassified)
K971095 (Unclassified)
Product Code: K971088 (EFQ)
K971089 (KKX)
K971090 (KMF)
K971091 (KMF)
K971093 (MGP)
K971095 (EFQ)
Dated: Undated
Received: June 18, 1997

Dear Mr. Sanders:

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 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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kits and trays listed above have either been determined as substantially equivalent under the premarket notification process

(Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kits and trays. 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 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

In addition, we have determined that your device kit contains alcohol swabsticks, PVP swabsticks, alcohol prep pads, and PVP prep pads which are subject to regulation as drugs.

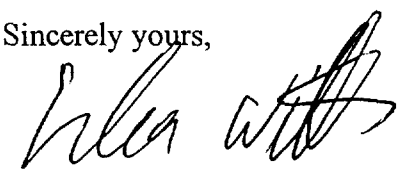
Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

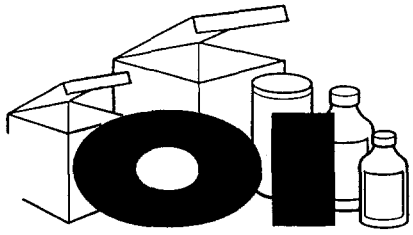
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809 for in vitro diagnostic devices), please contact the Office of Compliance at (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 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



OPPORTUNITY, INC.

510(k) Number: K971091

Device Name: Opportunity Tracheostomy Care Kit

INDICATIONS FOR USE:

Opportunity Inc.'s Tracheostomy Care Kit is intended for use by a licensed professional or other medical personnel as deemed appropriate by the using facility. The intended use of the medical products assembled in these kits will not change from the manufacturers original intended use. This kit is used for performing or assisting in performing tracheostomy procedures.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971091

Prescription Use ✓
(Per 21 CFR 801.109)

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