O.P.T. USA, INC.

235 SACKETT STREET • BROOKLYN, N.Y. 11231

LEADING TECHNOLOGY IN OPERATING TABLES

AUG 26 1997

K972810

"510(k) Summary"

Classification Name:	Table Operating Room, AC-Powered 79GDC
Common/Usual Name:	Mobile Operating Table
Proprietary Name:	OPT 80
Establishment Registration Number:	2437463
Classification:	Class I
Establishment Name and Contact Information:	O.P.T.-USA Inc. 235 Sackett Street Brooklyn, NY 11231 Contact Person: Maria Coria Tel. (718) 596-0848 Fax. (718) 596-0848

Safety and Effectiveness Information:

OPT tables are constructed under good manufacturing processes and meet the following performance and quality standards:
IEC 601-1
VDE 0750
IMQ

Substantial Equivalence:

The general use and technological characteristics of the device do not differ significantly from those of the currently marketed AMSCO Quantum 3080 SP 510(k) No. 930493. Attached is a table which compares the operational and safety features for the OPT 80 and the Quantum 3080SP. The devices have similar positioning capabilities, weight capacity, primary and back-up controls with manual override for emergency situations, caster locks, base material and overall size and weight.

It is the conclusion of O.P.T.-USA that the OPT 80 table is substantially equivalent to AMSCO's Quantum 3080SP table currently being marketed in the US.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Marie Coria
Managing Director
O.P.T. USA, Inc.
235 Sackett Street
Brooklyn, New York 11231

AUG 26 1997

Re: K972810
Trade Name: Mobile Operating Table OPT 80
Regulatory Class: I
Product Code: FQO
Dated: July 24, 1997
Received: July 28, 1997

Dear Ms. Coria:

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.

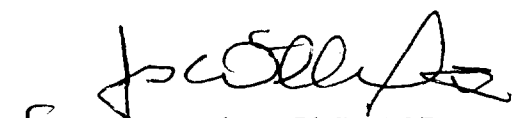
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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,



for 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): K972810

Device Name: Mobile Operating Table OPT 80

Indications For Use:

The OPT 80 Mobile Operating Table is designed for use during diagnostic examinations or surgical procedures to support and position a patient. It is made up of a column, movable tabletops and trolley. The tabletops allow trendelenburg, and reverse trendelenburg positioning, lateral tilting as well as back, leg and head plate movement. It has side rails for fitting additional accessories as may be required by a particular procedure. The table system is designed to hold a patient of 180 Kg. (400 Lbs.) in the positions described in the Instruction Manual and the attached Standard Equivalency Table.

Officine di Protesi Trento S.p.A provides an instruction manual to inform the customer on how to properly install and start the surgical table. To avoid failure, the user must follow the manufacturer's instructions for installation, use, cleaning and maintenance. There are secondary back-up operating devices to allow operation of the table should the primary control or power supply fail. Incorrect use and failure of the surgical table can lead to interruption of a surgical procedure and injury to the patient.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972810

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)