



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 26 2002

COSMED S.R.L.  
c/o Mr. Robert Schiff, Ph.D.  
President  
Schiff & Company  
1129 Bloomfield Avenue  
West Caldwell, NJ 07006

Re: K014262

Trade Name: Quark C12/Quark T12 Electrocardiograph for Stress Exercise Testing  
Regulation Number: 21 CFR 870.2340  
Regulation Name: Electrocardiograph  
Regulatory Class: Class II (two)  
Product Code: DPS  
Dated: December 26, 2001  
Received: December 27, 2001

Dear Dr. Schiff:

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.

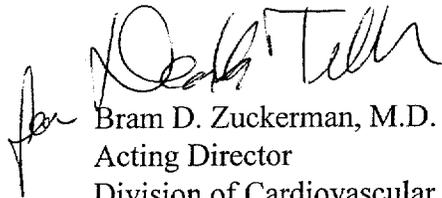
Page 2 - Mr. Robert Schiff, Ph.D.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.  
Acting Director  
Division of Cardiovascular  
and Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health.

Enclosure

K014262

510(k) PREMARKET NOTIFICATION  
COSMED SRL, ITALY  
COSMED QUARK C12 AND QUARK T12

**STATEMENT OF INDICATION FOR USE**

510(k) Number (if known): Not assigned yet  
Device Name: Quark C12 / Quark T12 stress exercise testing  
electrocardiograph

Indications for Use:

The COSMED Quark C12 (Quark T12 in telemetric version) is an electrocardiograph designed for cardiological stress testing, or cardiopulmonary stress testing, if used integrated with a COSMED metabolic cart (Quark b<sup>2</sup>, Quark PFT ergo or K4 b<sup>2</sup>).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K014262

Prescription use X or Over-the-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109) (Optional format 1-2-96)