DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 4 2001

Ms. Lois Nakayama
Manager, Quality Assurance
Tosoh Medics, Inc.
347 Oyster Point Boulevard, Suite 201
South San Francisco, CA 94080

Re: k012820
Trade/Device Name: AIA-PACK® cTNI 2nd Gen Troponin I Assay
Regulation Number: 21 CFR 862.1215, 862.1150
Regulation Name: Creatine Phosphokinase/Creatine Kinase or Isoenzymes Test System, Calibrator
Regulatory Class: Class II
Product Code: MMI, JIT
Dated: October 31, 2001
Received: November 5, 2001

Dear Ms. Nakayama:

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 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) 594-4588. 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 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TOSOH MEDICS, INC.
TOSOH

PREMARKET NOTIFICATION K012820

INDICATIONS FOR USE STATEMENT

AIA-PACK cTnI 2nd-Gen Troponin I Assay

AIA-PACK cTnI 2nd-Gen is designated for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of cardiac troponin I (cTnI) in human heparinized plasma on specific TOSOH AIA System analyzers. Cardiac troponin I measurements are used as an aid in the diagnosis of acute myocardial infarction (AMI).

Thomas C. Donat for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012820

Prescription Use X

Attachment I

347 Oyster Point Blvd., Suite 201, South San Francisco, California 94080 Tel: 650/615-4970 Toll Free: 1-800/248-6764 Fax: 650/615-0415