<This English translation was prepared with efforts to better translation, however, in case of inconsistency, the original Japanese text shall prevail.>

March 31, 1997
YAKUHATSU No. 479

To: Prefectural governors
From: Director General, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare
Re: Handling of the data of clinical studies for medical devices conducted in foreign countries

Handling of the data of clinical studies conducted in foreign countries, in application for approval of manufacture (or import) of medical devices, has been in accordance with YAKUHATSU Notification No. 660 by Director General of the Pharmaceutical Affairs Bureau dated June 29, 1985 "Handling of the data of clinical studies for pharmaceuticals etc. conducted in foreign countries". The decision has been made to handle the data as described below, from now on, please note it and thoroughly inform to the manufacturers and importers concerned under your jurisdiction.
Please note that a copy of this notification is being sent to Chief Executive of Japan Association for the Advancement of Medical Equipment, Chairperson of Japan Federation of Medical Devices Associations, Chairperson of Medical Devices Subcommittee, American Chamber of Commerce in Japan and Chairperson of Medical Devices Committee, European Business Council in Japan.

1. Acceptance of foreign clinical study data

Data of clinical studies conducted in foreign countries (hereinafter referred to as "foreign clinical study data"), in case it meets all the requirements stipulated in Attached table, shall be accepted as application material to be reviewed for approval of manufacture (or import) of medical devices.
In addition, domestic clinical study data that have been required as supplemental data for implantable medical devices that could affect biocompatibility are not, in principle, needed to be submitted, except for those medical devices with new structure and used for new treatment etc. that is not yet established in Japan.

2. Others

(1) Date of application

This notification shall be applied to applications made on or after March 31, 1997 for approval of manufacture (or import) of medical devices.

(2) Revision of the notification

With the enforcement of this notification, "2: Regarding medical devices" in Notification No. 660 by Director General of the Pharmaceutical Affairs Bureau dated June 29, 1985 "Handling of the data of clinical studies for pharmaceuticals etc. conducted in foreign countries" shall be deleted and "Japanese GCP principles for pharmaceuticals and Japanese GCP principles for medical devices or" in the left column of the third row of the table in "3: Acceptance requirements and related notes" shall be changed to "Japanese GCP principles for pharmaceuticals or".

Attached table

Acceptance requirements for foreign clinical study data and related notes

	Acceptance requirements	Related notes on application
1	Methods for the clinical study and clinical evaluation etc. meet the Japanese standards or guidelines, or are applicable to medical practices in Japan.	In case methods for the clinical study and clinical evaluation etc. don't meet the Japanese standards or guidelines, the characteristics of medical practices in the county where the clinical study was conducted should be made clear so that its applicability to Japanese medical practices can be properly evaluated.
2	Studies were conducted in reliable medical institutions such as public institutions or medical institutions attached to universities, and by researcher(s) with experience and ability to conduct such studies properly.	For the researcher(s) who developed the foreign clinical study data, materials showing their ability to conduct the studies properly (academic background, qualification, history of presentation in academic conferences, list of the academic societies they belong to etc.), and for the medical institutions, materials showing their reliability should respectively be attached to the application.

3	Studies were conducted in accordance with proper procedures and methods (adherence to the Declaration of Helsinki of the World Medical Association and compliance with Japanese GCP principles for medical devices or any foreign standards equivalent to or better than them).	Materials showing that the clinical study was conducted in accordance with proper procedures and methods (including Clinical Trial Protocol) should be attached to the application.
4	Raw data including individual case records and statistical analysis records that served as a basis for clinical study data should be available for inspection as needed.	Reliability of clinical study data may be subject to an examination in appropriate manner such as on-site inspection and submission of raw data. Therefore, data etc. necessary for the examination should be organized and managed properly. Clinical study data have to contain in it a signature by the person(s) who conducted the study, stating that the data was developed based on the study conducted by the signer(s). However, in case the person is unable to put his/her signature on the data because of unavoidable reason such as he/she is already dead, a document explaining the reason should be attached.
Others		Materials regarding foreign clinical study data etc. should be accompanied by complete and accurate Japanese translation. Also, qualification and professional career of the translator(s) should be provided.