

UNITED STATES INTERNATIONAL TRADE COMMISSION  
Washington, DC

Investigation No. 332-474  
Medical Devices and Equipment: Competitive Conditions Affecting U.S. Trade in Japan and Other  
Principal Foreign Markets

AGENCY: United States International Trade Commission

ACTION: Institution of investigation and scheduling of hearing

EFFECTIVE DATE: April 3, 2006

**SUMMARY:** Following receipt on March 9, 2006, of a request from the Committee on Ways and Means of the U.S. House of Representatives (Committee) under section 332(g) of the Tariff Act of 1930 (19 U.S.C. (332(g))), the Commission instituted investigation No. 332-474, *Medical Devices and Equipment: Competitive Conditions Affecting U.S. Trade in Japan and Other Principal Foreign Markets*.

**BACKGROUND:** As requested by the Committee, the Commission will conduct an investigation under section 332(g) and prepare a report assessing competitive conditions affecting U.S. trade of medical devices and equipment in principal foreign markets.

In preparing its report, the Commission will, as requested, closely examine the regulatory conditions of competition affecting U.S. sales and trade of medical devices and equipment in Japan, and other principal foreign markets, for the most recent 5-year period. The Commission will focus on the main U.S. exports of medical devices and equipment to these markets during this period, and compare Japan's regulatory conditions to those of the other major foreign markets for U.S.-made medical devices and equipment.

This report will also include, to the extent possible, for the most recent 5-year period, (1) an overview of the global market for medical devices and equipment, including production, consumption, and trade; (2) profiles of the medical device and equipment industries in the United States and principal foreign producer countries; (3) an analysis of U.S. trade in medical devices and equipment with major competitor countries including a description of trade practices, regulatory measures such as product approvals, and government and private expenditures on medical research; and (4) an examination of bilateral and multilateral trade agreements that have addressed regulatory issues in major foreign markets, including Japan's, and the implications for the U.S. medical device and equipment industry.

The Commission will provide its report to the Committee by March 9, 2007.

**FOR FURTHER INFORMATION, CONTACT:**

Co-Project Leader, Christopher Johnson (202-205-3488 or [christopher.johnson@usitc.gov](mailto:christopher.johnson@usitc.gov))  
Co-Project Leader, Heather Sykes (202-205-3436 or [heather.sykes@usitc.gov](mailto:heather.sykes@usitc.gov))

Industry-specific information may be obtained from the above persons. For more information on legal aspects of the investigation, contact William Gearhart of the Commission's Office of the General Counsel at 202-205-3091 or [william.gearhart@usitc.gov](mailto:william.gearhart@usitc.gov). The media should contact Margaret O'Laughlin, Office of External Relations at 202-205-1819 or [margaret.olaughlin@usitc.gov](mailto:margaret.olaughlin@usitc.gov). Hearing impaired individuals are advised that information on this matter can be obtained by contacting the TDD terminal on 202-205-1810. General information concerning the Commission may also be obtained by

accessing its internet server (<http://www.usitc.gov>). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS-ONLINE) at <http://edis.usitc.gov/hvwebex>.

**PUBLIC HEARING:** A public hearing in connection with this investigation will be held beginning at 9:30 a.m. on July 11, 2006, at the United States International Trade Commission Building, 500 E Street SW, Washington, DC. All persons have the right to appear by counsel or in person, to present information, and to be heard. Persons wishing to appear at the public hearing should file a letter with the Secretary, United States International Trade Commission, 500 E St., SW, Washington, DC 20436, not later than the close of business (5:15 p.m. EST) on June 27, 2006, in accordance with the requirements in the "Submissions" section below.

**WRITTEN SUBMISSIONS:** In lieu of or in addition to participating in the hearing, interested parties are invited to submit written statements or briefs concerning this investigation. All written submissions, including requests to appear at the hearing, statements, and briefs, should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW, Washington, DC 20436. Any prehearing statements or briefs should be filed not later than close of business, June 29, 2006; the deadline for filing posthearing statements or briefs is close of business, July 25, 2006. All written submissions must conform with the provisions of section 201.8 of the *Commission's Rules of Practice and Procedure* (19 C.F.R. 201.8). Section 201.8 of the rules requires that a signed original (or a copy designated as an original) and fourteen (14) copies of each document be filed. In the event that confidential treatment of the document is requested, at least four (4) additional copies must be filed, in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business information). The Commission's rules do not authorize filing submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the rules (see Handbook for Electronic Filing Procedures, [ftp://ftp.usitc.gov/pub/reports/electronic\\_filing\\_handbook](ftp://ftp.usitc.gov/pub/reports/electronic_filing_handbook)).

Any submissions that contain confidential business information must also conform with the requirements of section 201.6 of the *Commission's Rules of Practice and Procedure* (19 C.F.R. 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the "confidential" or "nonconfidential" version, and that the confidential business information be clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available in the Office of the Secretary to the Commission for inspection by interested parties.

In its request letter, the Committee stated that it intends to make the Commission's report available to the public in its entirety, and asked that the Commission not include any confidential business or national security confidential information in the report it send to the Committee. The report that the Commission sends to the Committee will not contain any such information. Any confidential business information received by the Commission in this investigation and used in preparing the report will not be published in a manner that would reveal the operations of the firm supplying the information.

Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Secretary at 202-205-2000.

By order of the Commission.

Marilyn R. Abbott  
Secretary to the Commission

Issued: April 3, 2006