

Implantable Medical Devices

Summary

Taiwan's medical device market is growing rapidly as the island's increasingly affluent population has more to spend on healthcare. In Taiwan, the overall medical device market is projected to grow at a rate of 3-5 percent per year while implantable medical devices grow at an annual rate of 6-10 percent. Most implantable devices are imported from the United States, Germany, and other European countries.

The national healthcare insurance program covers 98 percent of the eligible population, and provides reimbursement for a wide range of therapies. However, the system is under critical financial strain and the implementation of the so-called "Global Budget Program" is ushering in more stringent reimbursement standards that may lessen market growth, especially for high end products and services.

Recent insurance reimbursement cuts scheduled for July 1st of this year may lessen the demand for implantable medical devices. Reimbursement price cuts for AICD (automatic implantable cardioverter defibrillator) and (PTCA) balloon catheters will be 20% and 40% respectively.

Taiwan is a producer and exporter of disposable items and low-end devices. Due to the expectation that all medical equipment will be backed by an extended maintenance contract, there is virtually no market for refurbished items. Nevertheless, Taiwan's market offers ample opportunities for U.S. firms to profit from a strong and growing demand for advanced medical supplies.

Market Overview

The demand for improved lifestyles has driven a large number of programs aimed at preventing chronic diseases. Additionally, the number of senior citizens over 65 reached 9.48% (2.1 million) of the total 22.69 million population in 2004. An aging population combined with other factors such as high population density (622 people per square kilometer) has brought the National Healthcare Expenditure (NHE) to 6.26% of the GDP. In 2004, the average per capita expenditure on healthcare was US\$847 of a total per capita GDP of \$13,529. The ten leading causes of death were: malignant neoplasm; cerebrovascular disease; accidents and adverse effects; heart disease; hypertension disease; chronic liver disease and cirrhosis; bronchitis, emphysema and asthma; diabetes mellitus; tuberculosis; and suicide.

Statistical data of implantable medical devices in Taiwan:

	2003	2004	2005(e)
Total Market Size	89.3	115.7	123.4
Total Local Production	10.1	11.2	12.4
Total Exports	0.	1.4	1.5
Total Imports	79.2	105.9	112.5
Imports from the U.S.	39.4	47.0	46.7

Source: Industrial Technology Intelligence Service: Custom Statistics

Notes: Data are in millions of USD. The exchange rate (1USD=NTD) for 2003 was NT\$34.40; for 2004, NT\$33.47; and for 2005, NT\$31.50.

2004, Import market share (Percent for USA and major competitors)

USA 44.41%, Germany 10.78%, Netherlands 7.12%, Switzerland 6.40%, and Japan 6.34%

Market Trends

The Taiwan market for implantable medical devices has been growing rapidly as a result of Taiwan's growing elderly population and patients' increased awareness of new implant technologies. New innovations in medical devices have been a major force in improving the health of Taiwan's population. Investment in public healthcare has resulted in costly but noticeable advancements.

Cerebrovascular and heart disease are the two leading causes of death in Taiwan and have largely contributed to the demand for heart implants, such as pacemakers, AICD, and stent. Additionally, numerous cases of diabetes have created a rising need for artificial intraocular lens implants.

The Taiwan market's demand for implantable medical devices is forecasted to reach approximately US\$123.4 million in 2005. The market demand grew 29.5% from its US \$89.3 million total in 2003 to US\$115.7 million in 2004 due to innovative medical devices such as the ACID (automatic implantable cardioverter defibrillator) and the coronary stent system imported into Taiwan from the United States.

Import Market

The Taiwan Department of Health (DOH) regulates the importation of medical equipment, the National Bureau of Standards (NBS) formulates the design and safety standards for medical equipment and the Nuclear Science Council (NSC) inspects imported X-ray machines and radiation producing equipment.

According to industry statistics, the Taiwan market demand for hip and knee joints was estimated at about US\$ 23 million in 2005. Approximately 90% of this market for artificial joints is supplied by imports, only one local manufacturer supplying hip joints at a competitive price. The U.S. dominates the market for knee joints with approximately 65% of the import market share, (European countries garnering the remaining 35%.)

For years the U.S. suppliers have had an even larger presence in the import market for implantable medical devices, supplying over 90% of vascular grafts, 80% of ACID and artificial heart valves and 70% of intraocular lenses, hip prostheses, plates, nails, bone screws and bone cements. The latest cardiology innovation of drug eluting stents was introduced into Taiwan for PTCA surgeons in 2004. Additionally, the "Taxus Express" and "Cypher" coronary stent systems from Boston Scientific and Johnson & Johnson have full acceptance from local doctors and patients.

Owing to their good will, reliable quality and continuous efforts, U.S. companies have seized almost 60% of Taiwan's imported implantable medical devices market and their products are the preferred choice of local public hospitals. Current budgets have allowed

local hospitals to buy new products from trusted U.S. firms such as Medtronic, Johnson & Johnson, GE Medical, Boston Scientific, Stryker/Howmedica, Guidant, Bioment, and Zimmer. For such companies, good reputations mean substantial market shares.

Competition

Foreign firms supply most of the local demand for implantable medical devices. U.S. firms dominate the Taiwan market for artificial orthopedics joints with strong brand awareness, sales networks, distribution, and surgeon training. Currently, around 11 large international firms have succeeded in the artificial joints market as a result of their updated technology.

U.S. products have been recognized by local end-users for their quality, durability, and technological superiority to competing brands. However, the higher prices of American products and relatively stronger promotional efforts by foreign competitors such as Philips (Netherlands), Smith & Nephew (UK), Aesculap (Germany) Lima (Italy), centerpulse (Switzerland), and Siemens (Germany) have hindered further U.S. growth.

With a competitive pricing system, local manufacturers garnered a 10% market share in 2004, focusing on artificial joints for total knees and total hips. Nevertheless, U.S. firms' primary competition remains European.

End Users

The major customers for U.S. made health care products will continue to be both public and private hospitals. There are a total of 610 accredited hospitals (91 public, 483 private, and 36 Traditional Chinese) in Taiwan, of which 23 are medical centers, one is a would-be medical center and 66 are regional hospitals. Both the Department of Health and local level authorities control budgets for public and municipal hospitals.

In general, local public hospitals organize a purchasing committee, which consists of medical professors and doctors. This committee is in charge of establishing specifications and examining the purchasing requests. The major criteria for evaluating alternative suppliers are: product performance, product reliability, cost and after-sale service. Most public purchases must go through an open bidding process. Given Taiwan's purchasing power and the strong demand for imported medical equipment, stronger sales promotion would likely generate large revenues for U.S. firms.

Taiwan doctors invariably decide upon the brands of medical devices implanted in patients. Patient preference is never considered (by patients or doctors) prior to an operation. Therefore, the opinion of medical professionals is vital to establishing dominance in the medical device market. Thus far, U.S. brands have fared exceptionally well due to high numbers of Taiwan doctors studying in the U.S. as well a strong bias towards U.S. medicine at the international conferences Taiwan medical professionals regularly attend.

Best Prospects

HS Code	Product Description
9021-1100-004	Artificial joints

9021-3011-008	Total artificial heart
9021-3012-007	Artificial heart valve
9021-3020-007	Artificial vascular graft
9021-3031-004	Artificial intraocular lens
9021-3040-003	Artificial limbs carbon sets
9021-3050-000	Mammary prosthesis
9021-3060-008	Hip prosthesis, plates, nails, bone screws, bone cements
9021-3090-002	Other artificial parts of the body
9021-5000-006	Pacemakers for stimulating heart muscles, excluding parts and accessories
9021-9010-907	Other appliances, which are worn or carried, or implanted in the body, to compensate for a defect or disability
9021-9010-104	Automatic implantable cardioverter defibrillator

Market Access

U.S. medical suppliers selling products in Taiwan can distribute through local agents or through the establishment of a branch office in Taiwan. Because business practices and sales channels for expensive medical equipment in Taiwan are different from those in the United States, the most critical step for an exporting firm is finding a qualified local agent to market its products in Taiwan. This agent can also provide and gather market information, introduce new technological knowledge and equipment to local medical service providers, and train end-users to operate the equipment properly. Local agents with technical staff can provide efficient after-sales service.

Having a single reliable distributor cover the island exclusively is optimal given the close proximity of Taiwan's 100 or so hospitals and clinics. Having multiple distributors can lead to confusing representation and inconsistent pricing, which diminishes a firm's reliability. Changes in local distributors may also detract from the reputation of a foreign supplier. Therefore, working with a faithful local firm on a long-term basis is key to success. Payment between a local distributor and suppliers is usually done on an L/C basis, and deferred payment is also negotiable.

Market Entry

Pre-market Approval

Taiwan's Department of Health (DOH) regulates the importation of medical equipment. To market a medical device in Taiwan, the DOH's pre-marketing registration approval must be obtained before the Board of Foreign Trade (BOFT) of the Ministry of Economic Affairs (MOEA) issues an import license.

Taiwan is currently in the process of harmonizing domestic medical device classification with the commonly used international classification system. The DOH, following the USFDA's 21 Code of Federal Regulations (CFR), has classified medical devices into three classes: I, II, III.

The DOH announced a new registration requirement for medical devices on December 30, 2004. All medical devices (Class I, II, and III) must be registered in compliance with the amended Pharmaceutical Affairs Laws. The effective date is June 20, 2005. There are no significant changes in Class II and III registration procedures. Registration for

Class I, however, an updated announcement on June 16, 2005 is a GMP requirement for product registration except measurement & sterilization related products.

In addition, all medical devices will need to meet the Good Manufacturing Practice (GMP) requirement. DOH performs on-site inspection for local manufacturers and reviews quality system documentation (QSD) provided by foreign manufacturers. QSD is based on 20 requirements of GMP (ISO 13485).

GMP Requirements

Good Manufacturing Practice (GMP) requirements were introduced in February 1999. Newly established factories, and all new applications for pre-market approval, have to comply with GMP. There is a five-year period for those devices already registered and on the market when the rule went into effect.

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The DOH and USFDA signed an Exchange of Letters on January 9, 1998. According to this Exchange of Letters, the FDA agrees to provide purged copies of medical device Establishment Inspection Reports (EIRs) of United States manufacturers exporting to Taiwan upon request. As a result, medical devices manufactured in the U.S. are exempt from submitting quality system documentation if all of the following documents are included in a submission to DOH:

- (1) FDA Establishment Inspection Report (EIRs)
- (2) Certificate to Foreign Government
- (3) ISO 13485 Certificate.

Registration Requirements

A medical device manufacturer who wishes to export medical devices to Taiwan must assign a local agent/distributor in Taiwan who can apply, on the manufacturer's behalf, for a product license. The following documents (Quality System Documentation) are required, along with the application, to the Bureau of Pharmaceutical Affairs (BoPA):

- ③ A letter of authorization
- ③ A certificate of free sale
- ③ A leaflet (7 copies)
- ③ Two copies of quality control record (including testing methods and results) - required for all medical devices.
- ③ Form, structure, dimension, raw materials/ingredients, and quantity, performance, and purpose
- ③ A sample of the device (if feasible)
- ③ Clinical reports (2 copies) for newly developed devices or for approved medical devices with a new intended purpose or some special devices: such as implantable appliances, contact lenses etc.
- ③ Circuits and testing records of electrical installation (only for electrical equipment) (2 copies)
- ③ Instructions for operating security (only for electrical equipment) (2 copies)

- ③ Operating records of automatic measurement adjustment (only for automatic temperature adjusting equipment) (2 copies)
- ③ Testing records and certificate of radiation leakage (only for radioactive equipment) (2 copies)
- ③ Labels and instructions for use (Labels, instructions and dossiers must be provided in Chinese. English is not universally understood.)
- ③ Clinical Investigations (Hospitals in which clinical investigations will be conducted for unapproved medical devices should submit a clinical trial proposal to the DOH. After approval by the DOH, the hospitals will be able to import the device directly or to entrust a local agent to carry out the import procedures.)

Upcoming Trade Shows

Trade shows provide U.S. firms with an effective promotional vehicle in the Taiwan market. The following exhibition is annually scheduled during November at the Taipei World Trade Center:

MEDIPHAR Taipei – Taipei International Medical Equipment & Pharmaceuticals Show (November 10 to 13, 2005):

- Medical equipment & instruments
- Hospital supplies
- Computer products for medical purposes
- Educational equipment, diagnostic, medical materials
- Bio-tech products
- Pharmaceuticals
- Health care products
- Rehabilitative products

Information regarding the 17th Mediphar Taipei is as follows:

Event: Mediphar Taipei

Period: November 10-13, 2005

Organizer: Taiwan External Trade Development Council (TAITRA)

www.taiwantrade.com.tw

www.taipeiTradeShows.com.tw/Mediphar

Venue: Taipei World Trade Center, Exhibitor Hall

Address: No. 5, Hsinyi Road, Section 5, Taipei, Taiwan

KEY CONTACTS

U.S. firms wishing to learn more about Taiwan's medical devices market are encouraged to contact the following individuals for additional information:

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AIT's Commercial Section can be contacted at Tel: 886-2-2720-1550, Fax: 2757-7162.
AIT's Commercial Section is also on the World Wide Web at the following address:
<http://www.ait.org.tw>.

If this report has alerted you to a commercial opportunity in Taiwan, and you subsequently pursue it with successful results, please let us know. We track U.S. successes and want to know how our market reports and services are being used.