With the advances in medicine and technology, Americans expect the highest quality when it comes to medical devices. Unfortunately, that is not always the case.

Worldwide, demand for medical devices has exploded, with the United States claiming a large share of the demand as well as the devices. In many countries, testing and regulation standards are overseen by for-profit organizations. However, in America, the U.S. Food and Drug Administration (FDA) is tasked with the duty to govern companies who manufacture, package, label or import medical devices sold in the United States.

Regulation of Medical Devices

Yet even with strict FDA regulation in place, devices continue to be released to the public that later prove to cause harm or death. Implantable devices are expected to undergo clinical investigations prior to entering the market. It is not until they are released, however, that problems are recognized or acknowledged and the devices are ultimately recalled.

Product liability law exists to respond to the injuries and personal devastation that these defective devices cause.

According to research reported in the Archives of Internal Medicine, more than 70 percent of the recalled devices studied had been FDA approved without undergoing human testing. One third of the recalled medical devices used to treat heart disease.

Diana M. Zuckerman of the National Research Center for Women & Families and Steven E. Nissen of the Cleveland Clinic stated that the “findings reveal critical flaws in the current FDA device review system and its implementation that will require either congressional action or major changes in regulatory policy.”

Role of the FDA

Each year, the FDA receives a host of applications for approval of medical devices. If the approval process is handled properly, it should minimize the need for product recalls later.

To expedite the approval process, the FDA may implement a less stringent approval process for devices similar to already approved products on the market. In some cases, the FDA may depend upon manufacturers to provide evidence of the safety of their products. Though this allows the devices to be available sooner, millions of people could be put at risk for serious injury or death as humans become the testing subjects.

If a person suspects that faulty medical devices have caused significant harm or death to a loved one, it may be wise to consult with an experienced medical malpractice attorney. Under the law, an injured person or the family of a lost loved one due to defective medical equipment may be entitled to financial compensation.