K023173

DEC 18 2002

SECTION 10 ——— 510(K) SUMMARY

SUBMITTER DETAILS

APPLICANTS NAME: ANDREWS SURGICAL INNOVATIONS LTD

ADDRESS: 16 GROVE LAWN,
MALAHIDE,
Co. DUBLIN,
IRELAND.

TELEPHONE NUMBER: -353-87-239 2023

FAX: -353-1-663 6990

EMAIL: emmet@andrews-introducer.com

NAME OF CONTACT PERSON: EMMET ANDREWS

DATE OF APPLICATION: SEPTEMBER 9, 2002

DEVICE DETAILS

TRADE NAME: ANDREWS INTRODUCER™

COMMON NAME: SURGICAL FORCEPS

CLASSIFICATION NAME: FORCEPS, HTD

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCE IS CLAIMED

1. ROBERTS' FORCEPS
2. TUBE INTRODUCTION FORCEPS

DESCRIPTION OF THE DEVICE:

The Andrews Introducer™ is a reusable surgical forceps made of surgical steel that is specifically designed for the insertion of chest tubes. The Andrews Introducer™ is a three-limbed forceps and has three major features:

1. A pivot joint at the fulcrum that opens the tips when the handles are closed using the stronger gripping force of the hand. The extent to which the tips open has been limited so as to reduce the trauma to the intercostal muscle.
2. A vertical extension on each blade that creates a circular channel which is more accurately and appropriately shaped to allow easy passage of the chest tube. The distance between the vertical blades at the fulcrum is 10.7 millimetres, sufficient to accommodate the diameter of a 32 gauge chest tube, expanding to 22mm at the.
3. A third limb that is attached to the two main limbs through the pivot joint. It is held equidistant from the two main limbs by two leaf springs, which also close the tips when force is relieved from the handles. There is also a grip on the distal end of the third limb to hold the chest tube in position on the instrument for more rapid insertion once the channel has been created.

INTENDED USE OF THE DEVICE

INSERTION OF INTERCOSTAL CHEST TUBES

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Andrews Introducer™ are similar to those of the Roberts forceps in that they are both surgical forceps constructed of surgical steel and hinged on a pivot joint. The total length of the Andrews Introducer™ and the length of the section of the instrument that is inserted into the patient are similar to the Roberts forceps.

The additional technological characteristics of the Andrews Introducer™ are similar to the Tube Introduction forceps. They both contain a reverse pivot joint that opens the tips of the forceps when the handles are closed. A third arm is employed in each forceps to help guide the relevant tube into the dissected channel. A leaf spring is also used in the Tube Introduction forceps to maintain the forceps in the closed position.

The Tube Introduction forceps also makes use of vertical extensions on each of the blades to create a more appropriately shaped channel for the tube being inserted.

SUBSTANTIAL EQUIVALENCE BASED ON CLINICAL PERFORMANCE DATA

A clinical feasibility study of the use of the Andrews Introducer™ in an elective surgical setting was undertaken. Chest tubes that were required as part of elective cardiothoracic operations, usually inserted using a Roberts forceps, were instead inserted using the Andrews Introducer™. The primary end-point was successful and accurate placement of the chest tube. The operators also completed a questionnaire rating defined aspects of the procedure.

Thirty patients (19 male, 11 female; median age 61.5 years (range 16-81)) had chest tubes inserted using the Andrews Introducer™. The chest tube was inserted successfully without the trocar in all cases and there were no complications. Use of the Andrews Introducer™ rated as significantly easier relative to experience of use of the Roberts forceps in all specified aspects.

The Andrews Introducer™ can be used to insert intercostal chest drain safely and efficiently without using the trocar or any other instrument.

CONCLUSIONS

The Andrews Introducer™ is a reusable surgical forceps specifically designed for the insertion of chest tubes. It has been tested in a clinical trial. Substantial equivalence is claimed to the Roberts forceps, the forceps that is currently used for inserting chest drains, and the Tube Introduction forceps, a specifically designed forceps for the insertion of tubes into the trachea.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Andrews Surgical Innovations, LTD.
Emmet Andrews
16 Grove Lawn
Malahide
Co. Dublin
Ireland

Re: K023173
Trade/Device Name: Andrews Introducer, Model ASI01
Regulation Number: 878.4800
Regulation Name: Manual surgical instrument
Regulatory Class: Class I
Product Code: MDM
Dated: September 9, 2002
Received: September 23, 2002

Dear Mr. Andrews:

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 Section 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), please contact the Office of Compliance at (301) 594-4659. 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 Part 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,

Miriam C. Provost

FOR Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Andrews Surgical
Innovations
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Re:	**510(k) Number:**	**K023173**
	Product:	**Andrews Introducer**
	Model:	**ASI01**

INDICATION FOR USE FORM/STATEMENT

The Andrews Introducer™ is specifically designed for the insertion of intercostal chest tubes.

Miriam C. Provost
Division Sign-Off
Division of General, Restorative
and Neurological Devices
510(k) Number K023173

Registered Address: 16 Grove Lawn, Malahide, Co. Dublin, Ireland.

Website: www.andrews-introducer.com Telephone: -353-87-239 2023. Email: info@andrews-introducer.com