

**SECTION 5:**

**510(k) SUMMARY**

**MUL 1 5 2010**

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**Contact Person:** Mike White  
Product Development Director

**Date Summary Prepared:** 08 January 2010

**Trade Name:** LogiFlex Laparoscopic Band Positioning Device

**Common Name:** Endoscope and accessories

**Classification Name:** Laparoscope, General and Plastic Surgery  
(21 CFR 876.1500, Product Code GCJ).

**Equivalent to:** Logic Monopolar Laparoscopic Scissors – Surgical Innovations plc  
(K063485).

Modular Endoscopy Laparoscopic Scissors, Grasping Forceps, Dissectors  
and Needle Holders – Allegiance Healthcare Corporation (K991928).

Goldfinger Blunt Dissector – Obtech Medical SARL  
(Class I, 510(k) exempt; 21 CFR 878.4800)

**Device Description:** The LogiFlex Laparoscopic Band Positioning Device is a sterile, single-use, laparoscopic, blunt dissection instrument. It comprises a shaft with a distal articulating tip incorporating a slot that forms a hook for capturing suture threads and tubing. The LogiFlex Laparoscopic Band Positioning Device is designed to be connected to and used with the reusable, ratchet handle of the Logic Monopolar Laparoscopic Scissors in order to effect articulation of the distal tip. The LogiFlex Laparoscopic Band Positioning Device is not designed to be used with an electrocautery connection.

**Intended Use:** The LogiFlex Laparoscopic Band Positioning Device is indicated for use in laparoscopic procedures for blunt dissection between tissue layers, to pull suture threads, to pull tubing and to generally assist with the placement of a gastric band.

**Substantial Equivalence:** Determination of substantial equivalence for the LogiFlex Laparoscopic Band Positioning Device was based on comparison to the predicate devices in terms of intended use, indications for use and device technological characteristics, such as design features, materials of composition, principle of operation and presentation. The LogiFlex Laparoscopic Band Positioning Device is substantially equivalent to the Logic Monopolar Laparoscopic Scissors and the Modular Endoscopy Laparoscopic Scissors, Grasping Forceps, Dissectors and Needle Holders in terms of modularity of construction and intended use. The LogiFlex Laparoscopic Band Positioning Device is substantially equivalent to the single use insert components of the Logic Monopolar Laparoscopic Scissors in terms of the design, materials of construction, and principle of operation of the handle connection mechanism and the actuation mechanism. The LogiFlex Laparoscopic Band Positioning Device is substantially equivalent to the Goldfinger Blunt Dissector in terms of the indications for use and the design, materials of construction and principle of operation of the articulating distal tip.

## **Nonclinical tests summary**

### **1. Bench Testing**

#### **Distal Tip Pull Testing**

For this test the input criteria was determined to be:

- A tensile axial load > 2kg when pulling suture.
- Product straightens to -5° to 0° for cannula introduction / removal.
- Product articulates to ≥ 90° to allow positioning around the esophagus.

The pass results in TN100309 (Exhibit 12) show that the pre-production LogiFlex laparoscopic band positioning device passes the input criteria, achieve a load of 2.96kg and articulating from 0° to 90°.

In TN100341 (Exhibit 16), further testing was carried out on production standard product (13 samples). The results show that the product has achieved a load of 2.6kg and articulating from 0° to 90°.

#### **Sideway force testing**

For this test the input criteria was determined to be:

- A sideway force ≥ 0.54kg when pulling suture.
- Product straightens to -5° to 0° for cannula introduction / removal.
- Product articulates to ≥ 90° to allow positioning around the esophagus.

The pass results in TN100310 (Exhibit 11) show that the LogiFlex laparoscopic band positioning device passes the input criteria, achieve a sideway force of 0.54kg (same as Goldfinger Blunt Dissector) and articulating from 0° to 90°.

#### **Crimped nipple pull out testing**

For this test the input criteria was determined to be:

- Crimped nipple to withstand 5kg amount of force.

The pass result in TN100341 (Exhibit 16) shows that the LogiFlex laparoscopic band positioning device passes the input criteria, achieving an average force of 5.23kg.

#### Tip deflection testing

For this test the input criteria was determined to be:

- Product straightens to  $-5^{\circ}$  to  $0^{\circ}$  for cannula introduction / removal.
- Product articulates to  $\geq 90^{\circ}$  to allow positioning around the esophagus.

The pass results in TN100341 (Exhibit 16) show that the LogiFlex laparoscopic band positioning device passes the input criteria to articulate from  $0^{\circ}$  to  $90^{\circ}$ .

#### Lifecycle testing

For this test the input criteria was determined to be:

- All 10 specimens to survive 2 irradiation cycles and 50 actuations (articulating from  $0^{\circ}$  to  $90^{\circ}$ ) without any mechanical defects.

The pass results in TN100326 (Exhibit 14) show that the LogiFlex laparoscopic band positioning device passes the input criteria to survive 2 irradiation cycles and 50 actuations without any mechanical defects.

#### Drop testing

For this test the input criteria was determined to be:

- Pass in accordance with pass criteria ASTM D4169-1996. After 100% inspection of product after dropping there should be no visible defects found in the product and the package seal should be intact.

The pass results in TN 100311 (Exhibit 15) show that the LogiFlex laparoscopic band positioning device passes the input criteria where the packaging is capable of maintaining the device in a sterile condition and free from damage during transit.

## **2. Shelf life: LogiFlex Accelerated Ageing Testing**

A 5 year accelerated shelf life study is completed with the LogiFlex Laparoscopic Band Positioning Device. The study has been performed in accordance with ASTM F1980-07 and involves ageing of packed, sterilized devices at  $53^{\circ}\text{C} \pm 4^{\circ}\text{C}$ , under which conditions, 6 weeks storage duration is equivalent to 12 months storage at ambient temperature. Thirty test samples at each time point are subjected to visual inspection of the seals (in accordance with ASTM F1886-98(2004)); 15 of these are subjected to burst strength testing (in accordance with ASTM F1140-07) and 15 to dye penetration testing (in accordance with ASTM F1929-98(2004)). The full report of this testing (ref. Technical Note 100312) is provided at Exhibit 9.

## **3. Sterilization Validation**

The gamma radiation sterilization process used for sterilization of the Logic Laparoscopic Band Positioning Device has been validated in accordance with ANSI / AAMI / ISO 11137-2:2006, using the VDmax<sup>25</sup> method, and is subject to quarterly re-validation. To achieve a SAL of  $10^{-6}$  a sterilization dose of 25kilogray must be applied to this product.

The full report of this testing (ref. Technical Note 100313) is provided at Exhibit 7.

## **4. Materials Biocompatibility**

From ISO 10993-1:2002, LogiFlex is an external communicating device with duration < 24 hours, therefore initial tests for consideration are:

1. Cytotoxicity
2. Sensitization
3. Intracutaneous reactivity.

### **1. Cytotoxicity Test**

The result has showed that the extract of the negative control (polypropylene filters) was non-cytotoxic to L929 cells under the conditions of this test. The extract of the positive control (rubber bands) was cytotoxic to L929 cells under the conditions of this test. Therefore, LogiFlex has been indicated to be non-cytotoxic.

The full report of this testing (ref. Technical Note 100314) is provided at Exhibit 10.

### **2. Local Lymph Node Assay in the mouse**

The result has showed that a stimulation of less than 3 was recorded for the polar and non-polar extract of the test item. Therefore, the polar and non-polar extracts of LogiFlex were considered to be a non-sensitiser under the conditions of the test.

### 3. Intracutaneous Reactivity test in the rabbit

The result has showed that the average reaction to the polar and non-polar test item extracts was considered not to be greater than the average reaction for the corresponding control at any observation period. Therefore, polar and non-polar extracts of the LogiFlex meet the requirements of ISO 10993-10:2002 Intracutaneous (Intradermal) Reactivity Test in the Rabbit; and considered to be non-irritant under the conditions of the test.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

JUL 15 2010

Surgical Innovations Plc.  
% Mr. Mike White  
Product Development Director  
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Leeds LS16 6QZ United Kingdom

Re: K100109

Trade/Device Name: LogiFlex Laparoscopic Band Positioning Device  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: Class II  
Product Code: GCJ  
Dated: July 07, 2010  
Received: July 12, 2010

Dear Mr. White:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

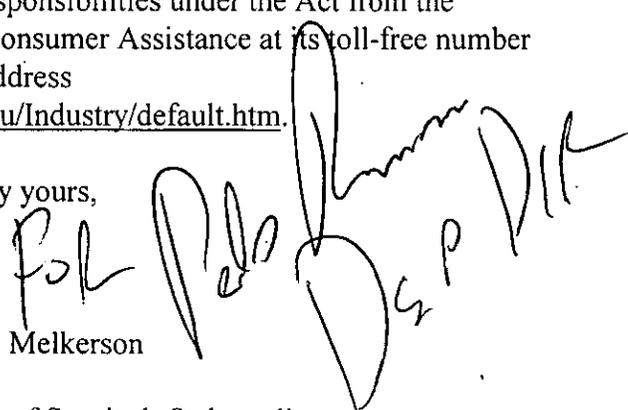
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name and title.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
And Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**SECTION 4:**

**INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): Not known

Device Name: LogiFlex Laparoscopic Band Positioning Device

Indications for Use: Use in laparoscopic procedures for blunt dissection between tissue layers, to pull suture threads, to manipulate tubing and to generally assist with the placement of a gastric band.

Prescription Use  X

AND/ OR

Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801 Subpart D)

(Per 21 CFR 801 Subpart C)

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Concurrence of CDRL Office of Device Evaluation (ODE)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number

K100109