SECTION 5: 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Information:

Category	Comments
Sponsor:	ESTECH, Inc. 2603 Camino Ramon Suite 100 San Ramon, CA 94583 Tel: 925-543-2110
Correspondent:	Tamer Ibrahim Vice President ESTECH, Inc
Contact Information:	Tel: 925-543-2110 Fax: 925-866-7117
Device Common Name:	Endoscope, Accessories
Device Proprietary Name:	Hawkeye™ Introducer System
Device Classification:	Class II, GCJ (21 CFR 876.1500)

Predicate Device Information:

Predicate Devices:	Flexview System (K062050)
Predicate Device Manufacturers:	Guidant, followed by Boston Scientific, now Maquet
Predicate Device Common Name:	Endoscope, Accessories
Predicate Device Classification:	21 CFR 876.1500
Predicate Device Classification Number:	Class II, GCJ

b. Date Summary Prepared

May 6, 2009

c. Description of Device

The Hawkeye family consists of two products; the ESTECH Hawkeye Magnetic Introducer System and the ESTECH Hawkeye Scope System.

The Hawkeye Magnetic Introducer System is comprised of three main components:

1. Hawkeye Magnetic Cannula Assembly
2. Magnetic Introducer
3. Malleable Stylet

Both Systems allow for endoscopic visualization within the thoracic cavity, blunt dissection, and facilitate the placement of surgical equipment.

These pieces may be packaged, sterilized and sold separately. They are single-use only.

d. Intended Use

The Hawkeye™ Introducer Systems, and accessories, are intended for use in minimally invasive surgery allowing access for delivery and placement of surgical instruments (e.g., ESTECH COBRA Adhere XL, AFfirm Pacing Probe). They are indicated for patients requiring blunt dissection of tissue including structures in the thoracic space.

e. Comparison to Predicate Device

The Hawkeye™ Introducer System is substantially equivalent in intended use, technology, design and materials to the Guidant FLEXView System (K062050).

ESTECH concludes that the devices are substantially equivalent.

f. Summary of Supporting Data

Biocompatibility analysis demonstrates that the device is in compliance with ISO 10993

Bench testing has demonstrated that the device meets the proposed product specifications.

Animal testing and cadaver testing demonstrated that the device can be used as intended and will meet the expectations of the medical community.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SEP 15 2009

Estech, Inc.
% Tamer Ibrahim
VP, R&D, RA, QA
2603 Camino Ramon, Suite 100
San Ramon, California 94583

Re: K091350
Trade/Device Name: Hawkeye™ Introducer Systems™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 26, 2009
Received: August 28, 2009

Dear Tamer Ibrahim:

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 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" (21CFR 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

510(k) Number (if known):

Device Name: Hawkeye™ Introducer Systems™

Indications For Use:

The Hawkeye™ Introducer Systems, and accessories, are intended for use in minimally invasive surgery allowing access for delivery and placement of surgical instruments (e.g., ESTECH COBRA Adhere XL, AFfirm Pacing Probe). They are indicated for patients requiring blunt dissection of tissue including structures in the thoracic space.

Prescription Use __X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for max

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices