JUN 16 2011

# 510(K) Summary

Section 05 K103783 - Additional Information Pad-type electrodes

## Submitter Information

FIAB SpA
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## Device name and classification

Trade name:
EURO DEFI PADS series of disposable multi-function electrodes

Common name:
defibrillation electrodes

Classification name:
Electrode, Electrocardiograph, Multi-Function (21 CFR 870.2360, Product code MLN)

## Predicate device

Lawfully marked devices to which it is claimed equivalence:

| Trade name | 510(K) holder | 510(K) number |
|---|---|---|
| Adult Radiotranslucent Multi-function Electrodes | Heart Sync LLC | K080421 |
| Adult Radiotransparent Multi-function Electrodes | Heart Sync LLC | K080421 |
| Pediatric Radiotranslucent Multi-function Electrodes | Heart Sync LLC | K081442 |

## Device description

FIAB EURO DEFI PADS series of disposable multi-function electrodes are made by a couple of pre-gelled self-adhesive pad-type electrodes consisting of foam backing, laminated metallic substrate, conductive hydrogel, cabling and molded connector. The electrodes are passive devices providing the conductive interface between the defibrillator and the patient's skin. Each couple of electrodes is permanently attached with lead wires that join together in a safety connector suitable for direct connection to devices - both monophasic and biphasic - of the main defibrillators brands nowadays present on the market.
The products are packaged in pairs inside water-vapor proof, heat sealed, non-transparent, aluminum/PE pouches.
FIAB EURO DEFI PADS series of disposable multi-function electrodes are available in the following versions: adult, adult radiotransparent, pediatric.

All products are intended to be used by medical staff only in not-sterile environment. All disposable devices are not-sterile and for single patient use only.

## Intended use

EURO DEFI PADS series of disposable multi-function electrodes are indicated for the following clinical applications:

- external defibrillation
- synchronized cardioversion
- cardiac stimulation
- ECG monitoring

EURO DEFI PADS series of disposable multi-function electrodes provide the conductive interface between the defibrillator and the patient's skin.
These devices are available with different connectors compatible for use with different defibrillators. All devices are non-sterile and for single-use only.

The pediatric model of EURO DEFI PADS disposable multi-function electrodes is intended for use on pediatric patient under eight years of age, or weighting less than 25 kg, the device is designed to deliver a maximum of 100 joule.
The adult model of EURO DEFI PADS disposable multi-function electrodes is intended for use on adult patients and children older than eight years or greater than 25 kg, the device is designed to deliver a maximum of 360 joule.
The radio-transparent adult model EURO DEFI PADS disposable multi-function electrodes for adult patient use only, is well suited for certain clinical applications involving radiographic viewing.

## Comparison to predicate

Safety and effectiveness of adult version:

| COMPARISON AREAS | **HEART SYNC Adult Radiotranslucent Electrodes (K080421)** | **FIAB EURO DEFI PADS Adult Electrodes** |
|---|---|---|
| **Indication for use** | For use as disposable electrodes on external defibrillators for monitoring, pacing, cardioversion and defibrillation | SAME |
| **Where used** | Hospitals and paramedic situation | SAME |
| **Basic features** | Radiotranslucent, non sterile, latex free, single use, self adhesive, in sealed foil pouch | Radiopaque, non sterile, latex free, single use, self adhesive, in sealed foil pouch |
| **Target population** | Adult patients | SAME |
| **Energy used and/or delivered** | For use on defibrillators whose output is classified as low power (360 joule maximum) | SAME |
| **Standard met** | 21 CFR 898.12 performance standard; ANSI/AAMI DF80:2003 standard | SAME |



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Safety and effectiveness of adult radiotransparent version:

| COMPARISON AREAS | **HEART SYNC Adult Radiotransparent Electrodes (K080421)** | **FIAB EURO DEFI PADS Adult Radiotransparent Electrodes** |
|---|---|---|
| **Indication for use** | For use as disposable electrodes on external defibrillators for monitoring, pacing, cardioversion and defibrillation | SAME |
| **Where used** | Hospitals and paramedic situation | SAME |
| **Basic features** | Radiotransparent, non sterile, latex free, single use, self adhesive, in sealed foil pouch | Radiotransparent except for wire-pad connection, non sterile, latex free, single use, self adhesive, in sealed foil pouch |
| **Target population** | Adult patients | SAME |
| **Energy used and/or delivered** | For use on defibrillators whose output is classified as low power (360 joule maximum) | SAME |
| **Standard met** | 21 CFR 898.12 performance standard; ANSI/AAMI DF80:2003 standard | SAME |

Safety and effectiveness of pediatric version:

| COMPARISON AREAS | **HEART SYNC Pediatric Radiotranslucent Electrodes (K081442)** | **FIAB EURO DEFI PADS Pediatric Electrodes** |
|---|---|---|
| **Indication for use** | For use as disposable electrodes on external defibrillators for monitoring, pacing, cardioversion and defibrillation | SAME |
| **Where used** | Hospitals and paramedic situation | SAME |
| **Basic features** | Radiotranslucent, non sterile, latex free, single use, self adhesive, in sealed foil pouch | Radiopaque, non sterile, latex free, single use, self adhesive, in sealed foil pouch |
| **Target population** | Pediatric patients whose weight is less than 25 kg | SAME |
| **Energy used and/or delivered** | Do not exceed a settings of 100 joules while defibrillating | SAME |
| **Standard met** | 21 CFR 898.12 performance standard; ANSI/AAMI DF80:2003 standard | SAME |

The products covered by this submission are substantially equivalent to other disposable multi-function electrodes, that are legally marked for this purpose. Specifically FIAB EURO DEFI PADS series of disposable multi-function electrodes are substantially equivalent to HEART SYNC electrodes.



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FIAB EURO DEFI PAD electrodes have the same intended use as the predicate device. There are no technical differences in the design, materials, packaging, and labeling compared to the predicate. The defibrillation pads meet the standards referenced above. They are produced and tested according to all requirements to guarantee safety and effectiveness (as shown in section 17 and 18 of the submission). According to the risk-benefit analysis (ISO 14971 standards), the risk has been deemed acceptable. The performance is expected to be the same as the predicate device (see section 12 of the submission). In addition to the descriptive characteristics the following tests were performed to establish substantial equivalence:

*Biocompatibility* – Biocompatibility testing of all patient contacting material was performed according to ISO10993-5 for cytotoxicity and 10993-10 for irritation and delayed-type hypersensitivity. The results were reported as passing by the NAMSA organization and are congruent with the predicate device.

*Component Compatibility* – Compatibility testing was conducted to ensure interoperability between the FIAB Euro Defi Pads and the listed defibrillators, pacers, and monitors. This included testing of the insertion and extraction forces of the physical connectors, amount of energy delivered through the pads, and the monitoring of a simulated heartbeat

*Electrical Standards* – Testing was conducted to meet AAMI/ANSI standard DF80:2003. The FIAB Euro Defi Pads passed the tests related to defibrillation pads

*Shelf-Life Testing* – Accelerated age testing was conducted to assure a shelf life of 30 months.



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

FIAB SpA
c/o Mr. Francesco Batistini
Counsellor of the Board
Via Costoli, 4
50039 Vicchio
Florence - Italy

JUN 16 2011

Re: K103783
Trade Name: FIAB Euro Defi Pads
Regulation Number: 21 CFR 870.5300
Regulation Name: DC-Defibrillator
Regulatory Class: Class II (two)
Product Code: LDD
Dated: May 10, 2011
Received: May 13, 2011

Dear Mr. Batistini:

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" (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/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,

M. J. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications For Use Statement

Section 04 K103783 - Additional Information Pad-type electrodes

**Indications for Use**

510(K) Number: K103783

Device Name: **EURO DEFI PADS series of disposable multi-function electrodes**

Indications For Use:

**EURO DEFI PADS series of disposable multi-function electrodes are indicated for the following clinical applications:**

- **external defibrillation**
- **synchronized cardioversion**
- **cardiac stimulation**
- **ECG monitoring**

**EURO DEFI PADS series of disposable multi-function electrodes provide the conductive interface between the defibrillator and the patient's skin.**
**These devices are available with different connectors compatible for use with different defibrillators. All devices are non-sterile and for single-use only.**

**<u>The pediatric model</u> of EURO DEFI PADS disposable multi-function electrodes is intended for use on pediatric patient under eight years of age, or weighting less than 25 kg, the device is designed to deliver a maximum of 100 joule.**

**<u>The adult model</u> of EURO DEFI PADS disposable multi-function electrodes is intended for use on adult patients and children older than eight years or greater than 25 kg, the device is designed to deliver a maximum of 360 joule.**

**<u>The radio-transparent adult model</u> EURO DEFI PADS disposable multi-function electrodes for adult patient use only, is well suited for certain clinical applications involving radiographic viewing.**

Prescription Use ___X___ AND /OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

M.J. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103783



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