DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 29, 2014

Biomedix, Inc.
Ms. Myra J. Bender
President
3895 West Vernal Pike
Bloomington, IN 47404

Re: K142097
Trade/Device Name: Biomedix SELEC-3 I.V. Administration Set
Regulation Number: 21 CFR 888.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: July 31, 2014
Received: August 1, 2014

Dear Ms. Bender:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K142097

Device Name

Biomedix SELEC-3 I.V. Administration Set

Indications for Use *(Describe)*

The SELEC-3 I.V. Administration Set is used to provide a pathway to deliver fluid into the body via the vascular system. This product is targeted for use by nurses and paramedics in pre-hospital, emergency room and field settings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

BIOMEDIX inc.
quality medical products

## SPECIAL 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

| | |
|---|---|
| **Submitter/Contact Information** | |
| **Name** | Biomedix, Inc. |
| **Address** | 3895 West Vernal Pike<br>Bloomington, IN 47404 |
| **Phone number** | (812) 355-7000 |
| **Fax number** | (812) 355-4507 |
| **Establishment Registration Number** | 1833470 |
| **Name of contact person** | Myra J. Bender |
| **Date prepared** | July 31, 2014 |
| **Name of device** | |
| **Trade or proprietary name** | Biomedix SELEC-3 I.V. Administration Set |
| **Common or usual name** | Intravascular Administration Set |
| **Classification name / Regulation number** | Set, Administration, Intravascular (21 CFR § 888.5440) |
| **Classification panel** | General Hospital |
| **Product Code(s)** | FPA |
| **Legally marketed device(s) to which equivalence is claimed** | SELEC-3 I.V Administration Set (K925645)<br>Biomedix, Inc. |
| **Reason for 510(k) submission** | Device modification |
| **Device description** | The Biomedix SELEC-3 I.V. Administration Set is a single-use, sterile device used for the administration of solutions and fully soluble drugs into the vascular system of a patient. |
| **Indications for use** | The SELEC-3 I.V. Administration Set is used to provide a pathway to deliver fluid into the body via the vascular system. This product is targeted for use by nurses and paramedics in pre-hospital, emergency room and field settings. |

## Summary of Technological Characteristics

The SELEC-3 I.V. Administration Set is constructed of biocompatible plastics. It incorporates a Selectable Drop Chamber that allows the user to choose between a flow rate of 10, 15, or 60 drops/cc at any time. Also included are Y-sites that allow the user to add medication. The intended use, basic design, and function are identical to the predicate device.

## Testing Summary

The SELEC-3 I.V. Administration Set has met Biomedix testing and acceptance criteria related to flow rate verification, leakage, microbial ingress, and pull force testing.

## Biocompatibility

Biocompatibility has been assessed in accordance with ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing. The SELEC-3 I.V. Administration Set has been categorized as an externally communicating device, indirect blood path, prolonged duration. Based on testing applicable to this categorization, biocompatibility has been demonstrated.

## Sterility

SELEC-3 I.V. Administration Sets are provided as sterile, single use devices that are individually packaged. The device is gamma sterilized through a validated process with the dose set in conformance with ANSI/AAMI/ISO 11137-2: 2012, "Sterilization of health care products- Radiation- Part 2: Establishing the Sterilization Dose," Method-VDmax25.

## Bacterial Endotoxins

The SELEC-3 I.V. Administration Set is monitored for bacterial endotoxins.

## Conclusion

The SELEC-3 I.V. Administration Set met all established acceptance criteria for design verification testing. Testing demonstrated that the device is safe and effective when used as intended.