K131247

Medical Flow Systems Ltd.

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ISO 9001:2008 ISO 13485:2003 Quality Systems Certified

# 510(K) SUMMARY FOR MFS – MEDICAL FLOW SYSTEMS' MULTIBOLUS II™

**DATE PREPARED:** MARCH 31, 2013

## 1. 510(K) OWNER NAME

AUG 1 4 2013

MFS – Medical Flow Systems Ltd.
ELT Building, Dora Industrial Zone, Shlomi 22832, Israel
Tel: +972 4 9808280, Fax: +972-4-9875565, E mail: info@mfs-medical.com.

**Contact person name:** Mr. Ofer Shay, Managing Director.
*Telephone:* +972-4-9114876, Fax: +972-4-9875565, E mail: offers@mfs-medical.com.

## 2. DEVICE NAME

**Common/Usual Name:** Disposable Pain Management System
**Proprietary/Trade name:** MultiBolus II™ (*'Parallel'* and *'In-line'* modules)
**Classification:** MFS's *MultiBolus II™* device has been classified as **Class II** device under the following classification names:

| Classification Name | Product Code | 21 CFR Ref. | Panel |
|---|---|---|---|
| Pump, Infusion, Elastomeric | 80-MEB | 880.5725 | General Hospital |
| Pump, Infusion, Pca | 80-MEA | | |

## 3. PREDICATE DEVICES

MFS's *MultiBolus II™* device is substantially equivalent to the following Predicate Devices:

**3.1** Baxter Healthcare Corporation *Multirate Infusor (LV and SV) with PCM,* cleared under 510(k) number **K051253** *and;*
**3.2** I-Flow Corporation *ON-Q Pump,* cleared under 510(k) number **K063530.**

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## 4. DEVICE DESCRIPTION

MFS's *MultiBolus II*™ is a semiautomatic disposable 100% mechanical device used as a complementary to MFS's pain management system to be controlled by the patient as prescribed **and set** by an authorized medical team member using either one or two catheters.
The device is to be integrated with the existing cleared MFS's elastomeric pumps and is designed to provide a bolus delivery of pain relief medication with or without parallel continuous basal flow.
The MultiBolus II™, together with the elastomeric pump creates a PCA (Patient Control Analgesia) infusion pump.

The *MultiBolus II*™ with *Parallel set* configuration is used when the delivery of a bolus medication is required to be executed parallel to a continuous basal flow.

The *MultiBolus II*™ *with In-Line set* configuration is used when the delivery of a bolus medication is required only.

Both configurations may be used during a dual catheter administration when a flow splitter such as; MFS's FlowSplitter™ (cleared within MFS's 510(k) number: K072053) device is assembled at the set exit port.
The device was developed by MFS to assist patients with pain management following surgical procedures or other pain managements. The device may be used in the hospital, at the clinic and at the home environment for out-patients subject to the physician decision.
MFS's *MultiBolus II*™ has the same indication for use and is substantially equivalent to the predicate devices selected by MFS in order to determine substantial equivalence as following detailed in this submission. The combination of these predicate-devices indication for use, technologies and performances supports our *MultiBolus II*™ substantial equivalency.

Body contact materials were evaluated for biocompatibility with accordance to *FDA's Memorandum – #G95 1, May 1, 1995* and *ISO 10993-1:2009.*

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## 5. INTENDED USE

The MultiBolus II™ is intended to provide intermittent delivery of medication on patient demand, using patient control module allowing bolus doses, at relatively rapid velocity in parallel to a continuous basal flow or without continuous basal flow, to/or around surgical wound site and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, percutaneous, subcutaneous, intramuscular and epidural.

## 6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The MultiBolus II™ is a semi-automatic 100% mechanical device to be activated by the patient after integrating with one of MFS's cleared elastomeric pumps (SmartBlock™ or SmartInfuser™).

MultiBolus II™ controls the medication flow through the system utilizing a built-in hydraulic mechanism that responds to the pressure differential between the pressure at the bolus device internal reservoir and the pressure at the pumps' reservoir. This mechanism enables an automatic medication filling into the bolus' reservoir when becomes empty, and to eliminate any flow out of the bolus device when not being activated and/or once the bolus' reservoir is empty ("stand-by" position).

**The comparison table with the predicate devices is following presented:**

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## Table 1: Comparison table with Predicate Devices

| Feature | MFS's MultiBolus II™ -New Device - | Baxter Helthcare Multirate Infusor 510(k) no. K051253 | I-Flow Corporation ON-Q Pump 510(k) no. K063530 |
|---|---|---|---|
| Intend of use | The MultiBolus II™ is intended to provide intermittent delivery of medication (such as local anesthetic and/or narcotics) on patient demand at relatively rapid velocity, parallel to a continuous basal flow or with no continuous basal flow, to/or around surgical wound site and/or close proximity to nerves for preoperative, periopertative and postoperative regional anesthesia and pain management. | The intended use of the Multirate Infusor with Patient Control Module includes slow, continuous, subcutaneous or epidural administration of pain medications. It may also include the slow, continuous infusion of pain medications directly into an intra-operative site, subcutaneously for postoperative pain management or the continuous infusion of a local anesthetic near a nerve for regional anesthesia. The Patient Control Module allows for intermittent bolus doses of pain medication on patient demand. Prescription | **1.** The ON-Q Pump is intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, percutaneous and epidural. *[2. The ON-Q Pump is...] - **Note:** Section 2 is irrelevant to MultiBolus II™ since it does not contain pump.* |
| Operation Principle | Mechanical, semi-automatic | Mechanical | Mechanical, semi-automatic |
| Safety | • No alarm<br>• Secure/lock of selected volume<br>• Sealing by Hydraulic independent valve to avoid continuous flow when not activated. | • No alarm<br>• Per-define volume<br>• Mechanical<br>• Mechanical closure (not necessarily sealed) thus continuous flow when not activated may be possible. | • No alarm<br>• Per-define volume<br>• Sealing by mechanical valve ("clamp technology") |
| Automatic filling after delivery | Yes | Yes | Yes |
| Performance Features | • Variety of volumes: | • Single Volume per | • Single Volume: |

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| Feature | MFS's MultiBolus II™ -New Device - | Baxter Helthcare Multirate Infusor 510(k) no. K051253 | I-Flow Corporation ON-Q Pump 510(k) no. K063530 |
|---|---|---|---|
| | 0ml, 3ml, 4ml, 5ml & 6ml.<br>• Lock Out flow rate: 6 ml/hr<br>• Velocity (through 21G Catheter): 6ml/minute.<br>• Accuracy – Volume (manual): +5%/-10%; Lock-Out: ±20% | device: 0.5ml or 2.0 ml.<br>• Lock-out flow rate 0.5ml/hr, 2ml/hr<br>• Velocity (through 21G Catheter): no data available (estimation: 1 ml/minute).<br>• Accuracy – No data | 5.0ml<br>• Lock-out flow rate per device: 5ml/hr or 10ml/hr<br>• Velocity (through 21G Catheter): 1.5 ml/minute *(tested by us)*.<br>• Accuracy – Volume: +10% / -20% Lock-Out: ±20% |
| Bolus Injection on patient demand | Yes. User needs to press once. | Yes. User needs to hold until bolus is completed. | Yes. User needs to press once. |
| Parallel Continuous flow and 'on-demand' bolus | Yes (the 'Parallel' model only) | Yes | Yes |
| Materials | Biocompatible Polymers, Elastomers per: ISO 10993 parts 1, 4, 5, 6, 10 & 11. | Similar | Similar |
| PCM – Patient Control Module | Yes | Yes | Yes |
| Use Environment | Hospital, clinic, home use | Same | same |
| Sterility | Sterile, EtO | Sterile, EtO | Sterile, EtO |

Based on the above comparison, it can be shown that in all major features MFS's *MultiBolus II™* is substantial equivalent to both legally marketed devices selected as predicate devices while our device infuse the medication at a relative higher velocity and also provides a complete sealing preventing any unintentional drug delivery through the bolus device when not activated or when being empty.

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## 7. PERFORMANCE DATA

MFS's *MultiBolus II*™ has been successfully tested through bench, usability and safety tests to support the determination of substantial equivalence with predicate devices.

**The summary of performance data is following presented in order to support substantial equivalency and safety/efficacy of our device:**

| No. | Test Name | Purpose | Method | Acceptance Criteria | Results | Conclusion |
|---|---|---|---|---|---|---|
| | | | **Functional Tests** | | | |
| 1 | Operating Cycles | Assuring the device capability to function in multi iteration (repeatedly) | 30 activation iteration of each device. | Activate semi-automatically according to spec in terms of functionality and in all volumes 3, 4, 5, & 6ml):<br>• Lockout time according to spec (not completely filled after the specified time).<br>• No parallel flow is allowed when not activated (scale monitor should show: 0.0). | • Device performed as intended.<br>• Under the test conditions the maximum volume tolerance was: -0.75ml. No result exceeding +0.0ml was detected.<br>• When nominal set to 6ml. no complete filling after the specified time occurred.<br>• Before activation scale monitor showed: 0.0. | Under the Test's conditions all acceptance criteria were met. |
| 2 | Priming | Verifying priming efficiency and 0.2μ filter effectiveness in trapping air bubbles in order to make priming for the parallel set | Conducting priming according to IFU in the basal path flow only (parallel set model) | • No air bubbles after the 0.2μ filter are allowed. | • No air bubbles after the 0.2μ filter were detected. | Under the test condition, all results met acceptance criteria. All air bubbles were trapped by the 0.2μ filter in priming for the |

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| No. | Test Name | Purpose | Method | Acceptance Criteria | Results | Conclusion |
|---|---|---|---|---|---|---|
| **Functional Tests** | | | | | | |
| | | model (option to exclude priming of the MultiBolus II™ device). | | | | parallel set model. |
| | | Verifying priming efficiency | Conducting priming according to IFU (in-line set model with the MultiBolus II™) | • No air bubbles in the tubing between the 0.2µ filter and the exit port after 1st activation are allowed.<br>• Volume of 2nd & 3rd activations should be as specified. | • No air bubbles after the 0.2µ filter were detected.<br>• Results were according to spec. | Under the test condition, all results met acceptance criteria. |
| 3 | Volumes | Verifying that actual volume is within the spec: | Measuring the actual infused bolus volumes with and without catheter after semi-automatic, manual activation (from set volumes of 3, 4, 5, 6 ml. | Actual infused bolus volume range should be according to spec. | Under the test's conditions the actual delivered volume in both semi-automatic and manual activation was according to spec. | Under the test condition, all results met acceptance criteria. |
| 4 | Velocity | Verifying actual velocity is within the spec | Measuring the actual velocity at 6ml volume with 21G catheter | Velocity should be at-least 5 ml/minute | Under the test's conditions all results were greater than 5ml/minute. | Under the test condition, all results met acceptance criteria. |
| 5 | Lock-Out Time | Verifying that actual re-filling time at nominal volume of 6ml is within the spec. | Verifying the actual filling time of 6 ml volume is between 48-72minutes *(state chosen as worst case representing all volumes)* | Filling time was between 48-72 minutes of nominal volume. | After the specified time reservoirs were not completely filled. After 72 min. all reservoirs were completely | Under the test condition, all results met acceptance criteria. |

| No. | Test Name | Purpose | Method | Acceptance Criteria | Results | Conclusion |
|---|---|---|---|---|---|---|
| **Functional Tests** | | | | | | |
| | | | | | filled. Volumes in semi-automatic mode were as specified. | |
| 6 | Leaks | Verify the device design withstand operation pressure | Reservoir and tubing connection withstand air pressure of 3 bar at 10 seconds | No leaks are allowed within at-least 10 seconds under 3 bar. | No leaks (stable pressure level) occurred during test's procedure. | Under the test condition, acceptance criteria was met. |
| 7 | Tube bonding | Verify the device's tubing connection withstand the forces during use. | Apply puling force of 1.5Kg on each tube for at-least 10 seconds. | • Tube remains connected to the device.<br>• No leaks after applying 1.5Kg. | During test, no tubing disconnections were detected and no leaks afterwards (according to same method as in test #6). | Under the test conditions, acceptance criteria was met. |
| 8 | Hydraulic check valve | Verify no flow through the device when not activated | Connect the device to filled-out reservoir for 14 days in a static position and evaluate against acceptance criteria. | During test period, the following are not allowed:<br>• Observed leaks;<br>• Gross weight of the device after 14 days is equal or up to 10 gram less than day 0 (baseline). | During the test's period, no leaks occurred. Maximum gross weight reduction was within defined acceptance criteria. | Under the test conditions, all tested samples met the acceptance criteria. |
| 9 | External force during use | Verify the device withstand reasonable external forces may be applied during use | Tested samples went through two free falls from one meter height. Then, they were filled with saline, activated according to IFU and observed against acceptance criteria. | During test, the following are not allowed:<br>• Cracks in the device cover (shells), or other plastic parts,<br>• Leaks,<br>• Device shall be properly activated and function. | Following the test conditions, no cracks, leaks or malfunctioning were detected. | Under the test conditions, all acceptance criteria were met. |

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| No. | Test Name | Purpose | Method | Acceptance Criteria | Results | Conclusion |
|---|---|---|---|---|---|---|
| **Functional Tests** | | | | | | |
| 10 | Shelf life equal to 1 year real-time (post accelerated aging) | Verify that the device will function well throughout its shelf life. | After accelerate aging for 45 days under 52°C to simulate 1 year shelf life, products were tested using 19-21G catheters by filling 6ml, priming, delivered volume weight, testing volume post 45&72minutes and activate bolus delivery (simulating the real use 5 times). | Under the test method the product should be operated and functioned according to its spec.<br>• Volume filled (per test 3),<br>• Lockout time (per test 5),<br>• No parallel flow, when not activated (per test 8),<br>• No visible cracks (per test 9),<br>• No visual leaks (per test 9). | Under the test method all filled volumes; lockout times; sealing state (no-parallel flow); no-cracks and leaks tests passed successfully. | All tested samples met the acceptance criteria and the product was qualified for 1 year shelf life. |

| No. | Test Name | Purpose | Method | Acceptance Criteria | Results | Conclusion |
|---|---|---|---|---|---|---|
| **Sterilization** | | | | | | |
| 11 | EtO Sterilization validation | Validate that the device may be sterilized for SAL $10^{-6}$ through EtO established cycle using overkill approach (also called: Half Cycle Method). | Per written protocol with accordance to ISO 11135-1:2007, Annex B. | With accordance to the following standards:<br>Bio Burden:<br>ISO 11737-1:2006<br>ISO 11135-1:2007<br><br>ETO/ECH Residues:<br>ISO 10993-7:2008<br><br>LAL Endotoxin:<br>USP 32:2009 <161><br>Transfusion and Infusion Assemblies and Similar Medical Devices *and;*<br>FDA's Guidance for Pyrojen & Endotoxins testing (Q&A), June 2012<br><br>Sterility:<br>ISO 11135-1:2007<br>ISO 11737-2:2010 | All tests' results were determined to be within the standards' acceptance criteria. More details are available in section 14 of this submission. | Following the sterilization validation, SAL $10^{-6}$ was established for MFS's *MultiBolus II*™ device. |

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| No. | Test Name | Purpose | Method | Acceptance Criteria | Results | Conclusion |
|---|---|---|---|---|---|---|
| **Packaging Integrity** | | | | | | |
| 12 | Packaging Integrity | • Verify that the shipping packaging the device provides sufficient protection to the device during shipping | Based on ASTM D5276-98 (drop) & ISO 2248 (vertical impact by dropping) | • All packages shall remain whole, unopened and complete.<br>• No physical damages to the sealed sterile unit are allowed. | None of the below defects have been occurred:<br>• No significant damage to shipping cases and internal boxes.<br>• No significant (tears, open) damage to sterile pouches.<br>• No functional damage to the device. | Following sterile unit's package integrity tests, all acceptance criteria were met and it was concluded that sterility will be maintained along the product's shelf life. |
| **No.** | **Test Name** | **Purpose** | **Method** | **Acceptance Criteria** | **Results** | **Conclusion** |
| **Packaging Integrity** | | | | | | |
| 12.1 | Packaging Integrity | • Verify sterile single unit package integrity in order to maintain product's sterility along **3 years** shelf life. | Exposing the packaging unit (single and shipping box) to all treatments undergo or might undergo in real-life (sterilization and drop). Products undergo real-time aging for 3 years under room temp: 22±1°C for three years and then tested for: visual defects, sterility, peel, dye and burst tests. | • Sterile package integrity tests per each test acceptance criteria (as further detailed in section 18 and appendix C of this submission. | All tested items met acceptance criteria for visual test, sterility test, and package integrity tests (peel, dye, burst) as further detailed in section 18 and appendix C of this submission. | Shelf life of 3 years real-time was established for the sterile unit package. |

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| No. | Test Name | Purpose | Method | Acceptance Criteria | Results | Conclusion |
|---|---|---|---|---|---|---|
| | | | **Usability** | | | |
| 13 | Usability (Physicians) | Validate that users of each group (physicians and home users) are capable to properly, safely and effectively set and operate the device and that the device is intuitive for activating. | Provide dummy regulating set with the device and filled reservoir (saline) to a person who "simulates a physician" (educated participant) accompany by physician IFU. Train this person on the device and then ask him to perform the following activating missions per IFU:<br>**1.** Assemble the regulating set to the reservoir (already filled with saline).<br>**2.** Prime the system.<br>**3.** Set and secure of the active volume.<br>**4.** Activate the device.<br>**5.** Re-set the device volume.<br>**6.** Permanently lock the active volume. | All 'physicians' participates shall operate the device through the "activation missions" successfully with according to the IFU. | • All participants have fulfilled successfully all "activation missions" according to the relevant accompanied IFU. | It was concluded from the usability results that the device is "usable" by its intended users (both physicians and patients) with accordance to IFU. The device met all test's acceptance criteria. |
| | Usability (Patients) | | Provide dummy devices connected to an elastomeric pump and filled with Saline.<br>Provide general information on the device and review the IFU for patients. Then, ask the patient to activate the device. | All 'patients' participants shall appropriately activate the device, i.e., squeeze the activating lever all the way until it 'clicks'. | | |

Tests results are supporting all labeling claims in order to establish substantial equivalency.

## 8. CONCLUSIONS

The evaluation of our device performances demonstrates that it is as safe and as effective as the predicate devices.

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 14, 2013

MFS-Medical Flow Systems Limited
Mr. Ofer Shay
Managing Director
ELT Building, Dora Industrial Zone, Shlomi
Shlomi Israel 22832

Re: K131247
Trade/Device Name: MultiBolus II™ Disposable Pain Management System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB, MEA
Dated: July 9, 2013
Received: July 12, 2013

Dear Mr. Shay:

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 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. 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,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indications for Use

**510(k) Number (if known):** K131247

**Device Name:** MultiBolus II™

[*Parallel MultiBolus II™* and; *In-Line MultiBolus II™* models]

**Indications for Use:**

The MultiBolus II™ is intended to provide intermittent delivery of medication on patient demand, using patient control module allowing bolus doses, at relatively rapid velocity in parallel to a continuous basal flow or without continuous basal flow, to/or around surgical wound site and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management.
Routes of administration may be intraoperative, perineural, percutaneous, subcutaneous, intramuscular and epidural.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
2013.08.12 15:13:46
-04'00'



*(Posted November 13, 2003)*

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
510(k) Number k131247