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# 510(K) – SUMMARY OF SAFETY AND EFFECTIVENESS

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| **Submitter:** | I-Flow Corporation<br>20202 Windrow Drive<br>Lake Forest, CA. 962630 |
| **Contact:** | Shane Noehre<br>Director, Regulatory Affairs<br>I-Flow Corporation |
| **Trade Names:** | ON-Q Pump, ON-Q Pump with Select-A-Flow,<br>ON-Q Pump with OnDemand |
| **Common Name:** | Elastomeric Infusion Pump |
| **Existing Device:** | I-Flow Elastomeric Pump (K052117) |
| **Design Change:** | This Special 510(k) submission proposes an increase in the maximum fill volume from 500 to 770 ml. |
| **Device Description:** | The *ON-Q Pump* consists of an elastomeric pressure source with an integrated administration line. Fill volumes range from 50 to 770 ml. Flow rates range from 0.5 to 250 ml/hr. The administration line typically consists of fixed flow rate control tubing or orifice but may contain any of the following optional features:<br>• Select-A-Flow component that provides a range of flow rates that may be dialed depending on the needs of the healthcare professional.<br>• Bolus component (e.g. OnDemand) that provides basal and/or bolus delivery.<br>• Y-adapter component that may split the administration line into two or more delivery sites. The Y-adapter component may also be used to provide a combination of options (such as both the Select-A-Flow and OnDemand components) for one delivery site.<br>• Air and particulate eliminating filter.<br>The pump may be sold as a kit with additional medical devices or accessories such as the following:<br>• Catheter, introducer needle, Tunneler, syringe, dressing, filling extension set, carry case, E-clip, nerve block accessories, etc. |
| **Indications for Use** | 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.<br>2. The *ON-Q Pump* is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared with narcotic only pain management. |
| **Technology Comparison:** | There is no change in fundamental scientific technology. The design remains the same as previously cleared devices. |
| **Conclusion:** | The *ON-Q Pump* with fill volumes up to 770 ml are substantially equivalent to the existing I-Flow elastomeric pumps currently marketed. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2007

Mr. Shane Noehre
Director of Regulatory Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, California 92630

Re: K063530
Trade/Device Name: ON-Q-Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: December 28, 2006
Received: December 29, 2006

Dear Mr. Noehre:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Applicant: I-Flow Corporation

510(k) Number (if known): K063530

Device Name: *ON-Q Pump*

**Indications For Use:**

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 also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

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)

[signature]

[illegible] Anesthesiology, General Hospital,
[illegible] Control, Dental Devices

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