# 510(k) SUMMARY

## JetPrep, Ltd.
## JetPrep Flushing Device

DEC 10 2012

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| Sponsor / Manufacturer: | JetPrep, Ltd.<br>71 Ha'Nadiv St.<br>Herzliya 46485<br>Israel<br>Phone: +972-9-950-6712<br>Fax: +972-9-950-6710<br>Contact: David Nitsan, CEO |
| Date Summary Prepared: | September 6, 2012 |
| Submitter / Representative: | John Smith, MD, JD<br>Hogan Lovells US LLP<br>Columbia Square<br>555 Thirteenth Street, NW<br>Washington, DC 20004<br>Phone: +1-202-637-5600<br>Fax: +1-202-637-5910 |
| Device: | Trade Name / Common Name: JetPrep Flushing Device<br>Classification Name: Endoscopic irrigation/suction system<br>Product Code: OCX<br>Classification Regulation: 21 C.F.R. § 876.1500 |
| Predicate Device: | JetPrep Flushing Device<br>JetPrep, Ltd.<br>K111274 |
| Purpose of the special 510(k) notice: | The JetPrep Flushing Device is a modification to cleared JetPrep Flushing Device (K111274). |
| Intended Use: | The JetPrep Flushing Device is intended for use as a flexible endoscopic accessory to apply legally marketed solutions for washing mucosal tissue in the gastrointestinal tract. |
| Device Description: | The JetPrep Flushing Device is a sterile, disposable, single use device, intended for use as flexible endoscopic accessory to apply legally marketed solutions for washing mucosal tissue in the gastrointestinal tract. |

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| Technological Characteristics: | The device is composed of a catheter with a spray tip on its distal tip. During operation, the catheter should be inserted into the endoscope working channel. The spray tip location can be manually controlled by the user to be positioned on the distal end of the endoscope working channel, and thus apply a funnel shaped irrigation spray pattern. The device does not impede aspiration of debris and fluids through the endoscope working channel while it remains within the endoscope. For providing irrigation fluids, the device should be connected to legally marketed irrigation pumps or manual syringe for endoscopy. This 510(k) notice adds an additional model of the device. |
| Performance Data: | The JetPrep Flushing Device has been subjected to extensive safety and performance validations prior to release. The device parts that come in contact with the irrigation fluids and/or the patient's tissue are composed of materials that were tested for biocompatibility. |
| Substantial Equivalence: | The modified JetPrep Flushing Device has the same intended use, principles of operation, and technological characteristics as the cleared JetPrep Flushing Device. The minor differences in the modified JetPrep Flushing Device do not raise any new questions of safety or effectiveness. Performance data demonstrates that the modified JetPrep Flushing Device is as safe and effective as the cleared JetPrep Flushing Device. Thus, the modified JetPrep Flushing Device is substantially equivalent to its predicate device. |

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

December 10, 2012

JetPrep, Ltd.
% John Smith, M.D., J.D.
Regulatory Counsel
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
WASHINGTON DC 20004

Re: K122740
Trade/Device Name: JetPrep Flushing Device
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCX
Dated: December 5, 2012
Received: December 5, 2012

Dear Dr. Smith:

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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number (if known): K 122740

Device Name: JetPrep Flushing Device

Indications for Use:

The JetPrep Flushing Device is intended for use as a flexible endoscopic accessory to apply legally marketed solutions for washing mucosal tissue in the gastrointestinal tract.

Prescription Use X AND/OR Over-The-Counter Use _____

(Per 21 C.F.R. 801 Subpart D) (Per 21 C.F.R. 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122740