



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

January 10, 2013

Xenolith Medical Ltd.  
% Mr. Ofer Zigman  
Head of Research and Development  
1 Leshem Street, PO Box 720  
KIRYAT-GAT  
ISRAEL 82000

Re: K123438  
Trade/Device Name: XenX™ Stone Management Device  
Regulation Number: 21 CFR§ 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: OCY, FFL  
Dated: December 31, 2012  
Received: December 31, 2012

Dear Mr. Zigman:

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,

**Herbert R. Lerner**

*Acting Director for:*  
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

**Attachment 1**

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**Labels and IFU's**

**Attachment 2**

**Indications for Use Statement**

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

K123438

**Device Name** XenX™ Stone Management Device

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**Indications for Use**

The XenX device is intended to be used endoscopically to bypass and entrap calculi from the urinary tract, to prevent retrograde migration of calculi during laser lithotripsy and to facilitate the placement of endourological instruments during diagnostic or interventional procedures.

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)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

**Herbert P. Lerner**

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(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and Urological Devices

510(k) Number

K123438