

16974428

JUL 30 1998

### 510(k) Summary (Revised)

1. Name of device: *DipStreak Urine Culture Device* (K974428)
2. Identification of the predicate device: the Savyon Diaslide Urine Culturing Device (510(k) no. K921045).
3. Description of the device: *DipStreak* comprises a plastic paddle with two types of agar attached back-to-back, housed in a closed transparent plastic tube. A ring with elongated prongs is attached to the end of the paddle so that there are prongs on each side of the slide. The ends of the prongs are dipped into the urine sample. Upon re-insertion into the plastic tube, the prongs are prevented from moving and the agar surfaces are inoculated with bacteria from the urine sample as the agar-coated paddle passes over the prongs. The result is a series of streaks of decreasing bacterial concentration which permits isolation of single colonies even when the original bacterial population of the sample was as high as  $10^7$  organisms per milliliter.
4. Intended use: the Novamed, Ltd. *DipStreak Urine Culture Device* is used for the isolation and enumeration of bacteria in urine.
5. Performance and design specifications: pathogenic bacteria found in urine samples at levels from  $10^3$  to  $10^7$  CFU/ml are detected accurately and consistently when using the *DipStreak Urine Culture Device*. Experimental evidence to support this claim is given in the application in the Precision Study.
6. Performance data: when compared to the predicate device in two studies comprising 522 clinical samples, the *DipStreak Urine Culture Device* demonstrated overall agreement of 96.4% at the cutoff level of  $10^4$  CFU/ml and 96.9% at the cutoff level of  $10^5$  CFU/ml. The *DipStreak Urine Culture Device* was also compared to traditional petri dish culture in a study of 1000 clinical samples. Sensitivity and specificity values for cutoff levels of  $10^4$  and  $10^5$  CFU/ml were all above 98.6%. Details of these studies are given in the application.
7. User quality control: quality control tests are performed on each lot of *DipStreaks* at the time of manufacture. Product users who wish to perform their own quality control may use the following procedure.
  - a. Prepare a suspension ( $10^4$ - $10^5$  CFU/ml) of each of the following organisms in sterile urine. Confirm the exact organism concentration by inoculating 10  $\mu$ l with a calibrated loop on reference plates of CLED and MacConkey agar.
  - b. Test the suspension according to the above Procedure.

#### TYPICAL CULTURE RESPONSE (after 24 hours at 37°C)

Strain	Growth rate	Colony Appearance	
		MacConkey	CLED
<i>E. coli</i> ATCC No. 25922	2-3 mm colonies can be seen within 12-14 hr	Red-purple colonies with smooth borders	Yellow colonies with smooth borders
<i>S. aureus</i> ATCC No. 25923	MacConkey -no growth CLED-1 mm colonies can be seen within 12-14 hr	No growth	Yellow colonies with smooth borders
<i>P. vulgaris</i> ATCC No. 13315	0.5-1 mm colonies can be seen within 16-20 hr	Colorless colonies with rough borders	Blue colonies with rough borders

If the device does not support the expected growth of organisms, it has deteriorated and should not be used.



JUL 30 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Gerald M. Slutzky, Ph.D.  
Director, Research and Development  
Novamed, Ltd.  
28 Pierre Koenig St.,  
Talpiot Industrial Area  
Jerusalem 91531 Israel

Re: K974428  
Trade Name: DipStreak Urine Culture Device  
Regulatory Class: I  
Product Code: JSI  
Dated: July 8, 1998  
Received: July 13, 1998

Dear Dr. Slutzky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

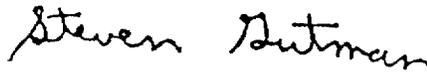
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K974428

Device Name: DipStreak Urine Culture Device

Indications For Use:

The Novamed, Ltd. **DipStreak Urine Culture Device** is used for the isolation and enumeration of bacteria in urine. A set of plastic prongs on the end of the device are dipped into the urine sample. The drops of urine which adhere to the prongs are then streaked across two different agar surfaces (CLED agar on one side, MacConkey agar on the other). A dilution effect takes place which allows the isolation of single colonies.

(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)

Woody Debaer  
(Division Sign Off)

Division of Clinical Laboratory Devices

510(k) Number K974428

Prescription Use X  
(Per 21 CFR 801.109)

OR

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

(Optional Format 1-2-96)