

K960578

SEP 5 1996

510(k) Summary
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- a.1. Diagnostic Hybrids, Inc.
1 President Street
Athens, Oh 45701
(614) 593-1784
Attn: J.L. Brown
Date of Preparation: February 1, 1996
- a.2. Trade Name: ELVIS™ HSV GOLD
Common Name: Enzyme Linked Virus Inducible System Tube Culture for Herpes simplex virus isolation and identification.
Classification Name: Not known.
- a.3. Classical "Gold" standard tube culture methods commonly used by many clinical laboratories for isolation and identification of HSV. Confirmation, where used, is by fluorescent antibodies directed against HSV antigens.
- a.4. The subject device consists of a mixed cell monolayer comprised of MRC-5 (Human Fetal Lung) and genetically modified Baby Hamster Kidney Cells (ELVIS™ HSV cells) which, when infected with HSV-1 or -2, are activated to produce and accumulate intracellularly the bacterial enzyme, beta-galactosidase. As in standard tube culture procedures, inoculated monolayers are examined daily for CPE. When CPE is observed, the monolayers are fixed and stained for the presence of beta-galactosidase. If blue cells are detected, indicating the presence of the enzyme which was induced by HSV, then the specimen is confirmed as being positive for HSV. If CPE is not detected by day 7 after inoculation, the monolayers are stained for the presence of pre-CPE, blue, HSV-infected cells. If none are found, the specimens are negative for HSV.
- a.5. Intended Use: The Test Kit provides the cells and reagents necessary for detection and identification of HSV in patient specimens.

a.6. A comparison of the technological characteristics:

	<u>Predicate devices</u>	<u>Subject device</u>
<u>Characteristics</u>	<u>Standard Tube Culture</u>	<u>ELVISTM HSV GOLD</u>
<u>In situ detection:</u>	<u>Yes</u>	<u>Yes</u>
Positive result indicated by:	CPE, confirmed by	CPE, confirmed by
	<u>Fluorescent Cells</u>	<u>Blue Colored Cells</u>
<u>Detection by:</u>	<u>Fluorescence Microscope</u>	<u>Light Microscope</u>
<u>Signal generated by:</u>	<u>Fluorescence</u>	<u>Beta-Galactosidase</u>

- b.1. The non-clinical tests consist of those directed at defining the shelf life of the test kit components, the analytical sensitivity and the specificity of the test kit.
- b.2. The clinical tests submitted consist of studies performed in 4 different laboratories on over 670 different specimens. The overall results show for the ELVIS™ HSV GOLD test a clinical sensitivity of 98.1% and a clinical specificity of 98.7% compared to the predicate tests. The specimens tested were those normally submitted to the respective institution for HSV testing; ELVIS™ HSV GOLD testing was performed on those specimens for which there was sufficient residual sample. The above test results demonstrate that the ELVIS™ HSV GOLD test is substantially equivalent to the predicate tests.
- b.3. The results from the clinical tests of ELVIS™ HSV GOLD , as well as the users' experience with the Test demonstrate that the device is safe and effective and performs at a level that is substantially equivalent to the predicate devices and standard clinical test methods employed at each Site.