BK060021

510(k) SUMMARY

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Manufacturer:

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Proprietary Name:	**Common Name:**
PROCLEIX® TIGRIS® System	TIGRIS Instrument or TIGRIS System

Device Classification:

The product classification for the PROCLEIX TIGRIS System is "Automated Bloodborne Pathogen Test Equipment "; Division of Emerging Transfusion Transmitted Diseases; Code MZA; Class II.

Predicate Device:

PROCLEIX® System for the PROCLEIX® WNV Assay (BK050042 cleared November 15, 2005).

Device Description:

The PROCLEIX TIGRIS System is an integrated nucleic acid testing system, which fully automates all steps necessary to perform the PROCLEIX WNV Assay from sample processing through amplification, detection, and data reduction. The instrument system includes hardware and software components to provide positive identification tracking of samples, control pipetting of donor sample and reagents, perform data reduction, and create reports.

Intended Use:

The PROCLEIX® TIGRIS® System is an integrated nucleic acid testing system which fully automates all steps necessary to perform the PROCLEIX ® Assays from sample processing through amplification, detection, and data reduction. The PROCLEIX Assays are qualitative *in vitro* nucleic acid amplification tests for the detection of pathogenic viruses in human plasma.

The PROCLEIX TIGRIS System is only intended for use with PROCLEIX Assays for *in vitro* diagnostic use that have package inserts with PROCLEIX TIGRIS System instructions. In the United States, this is limited to licensed PROCLEIX Assays.

Comparison to Predicate Device:

A comparison to the predicate device is provided below. Devices are substantially equivalent based on indications for use and technological characteristics.

The indications for use are identical to the predicate device (PROCLEIX System); however, the PROCLEIX TIGRIS System is fully automated, whereas, the PROCLEIX System is semi-automated requiring operator input at various steps throughout assay processing.

Both the PROCLEIX System (predicate device) and the TIGRIS System are used to screen the same sample types and can be used to test individual donor sample or pools.

Both Systems are based on the same technological characteristics. Like the PROCLEIX System, the TIGRIS System is an instrument and software platform designed to process all steps necessary to perform the PROCLEIX WNV Assay, from sample processing through amplification, detection, and data reduction. Both systems use the same ETF algorithm.

Differences between the two instrumentation systems include incubation times and temperatures to accommodate the differences in incubator types, and mixing steps. Additionally, the TIGRIS System requires the use of an automated Reagent Preparation Incubator (RPI), an optional piece of equipment with the PROCLEIX System. The TIGRIS System is designed with several layers of controls to ensure proper performance of the system.

Performance Data:

Both non-clinical (analytical) and clinical evaluations (blood donor population) were performed to compare assay performance of the TIGRIS System to the predicate device (PROCLEIX System). These studies are included in the PROCLEIX WNV BLA, STN 125121/0.

Non-clinical studies

Both systems demonstrated equivalent performance on the following non-clinical evaluations: analytical sensitivity studies, specificity studies on normal blood bank donor specimens and cadaveric specimens, specimen stability studies and non-specificity studies.

Clinical studies

Results of clinical studies were used to determine 1) the reproducibility of the PROCLEIX WNV Assay on the PROCLEIX TIGRIS System and 2) the performance of the PROCLEIX TIGRIS System compared to the PROCLEIX System when using the PROCLEIX WNV Assay.

Results of reproducibility testing of the PROCLEIX WNV Assay on both the TIGRIS and PROCLEIX Systems demonstrated reproducibility for both platforms with substantially equivalent overall percent agreement between platforms.

Results of clinical performance testing of the PROCLEIX TIGRIS System demonstrate substantial equivalence to the PROCLEIX System. Performance was determined by comparison of results from testing samples composed of WNV-negative or WNV-positive samples (as determined by nucleic acid testing) on both systems. Equivalent performance was determined by assessing agreement between the system results and the true status.