SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE RE: DOCUMENT NUMBER K093224

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.
   DensiCHEK™ Plus - K083536

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

   The Indication/Intended Use statement has not changed.

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   The modifications were:

   - The addition of yeast susceptibility test card, AST-YS, for use in conjunction with the DensiCHEK™ Plus Instrument.
   - The addition of AST-YS to *Table 2: Organism Suspension Range* in the DensiCHEK™ Plus Instrument User Manual to reflect that performance has been established for VITEK 2 AST-YS card and is now appropriate for use with the DensiCHEK™ Plus Instrument.
   - Removal of the following footnote from under *Table 2: Organism Suspension Range* in the DensiCHEK™ Plus Instrument User Manual: "Note: *The performance has not been established for the AST YS card."

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and

Item	Device: DensiCHEK™ Plus, Modified	Predicate: DensiCHEK™ Plus (K083536)
Similarities		
Intended Use	The DensiCHEK Plus instrument is intended for use with the VITEK® and VITEK® 2 Systems to measure the optical density of a microorganism suspension. The instrument provides values in McFarland units, proportional to microorganism concentrations. DensiCHEK™ Plus is indicated for use with polystyrene and glass test tubes and the reading range is 0.0-4.0 McFarland. The DensiCHEK™ Plus has application as an in vitro diagnostic device.	Same
Test Method	The DensiCHEK™ Plus uses an LED as the light source to measure the amount of bacteria suspended in liquid medium and convert that optical density into a McFarland standard. It then displays a digital reading of the McFarland unit.	Same
Inoculum	Saline suspension of organism	Same
Differences		
VITEK® / VITEK® 2 Products Appropriate for Use with DensiCHEK Plus (performance established)	GPI, GPS, GNI+, GNS, YBC, NHI, ANI, GN, AST GN, GP, AST GP, YST, **AST YS**, NH, ANC	GPI, GPS, GNI+, GNS, YBC, NHI, ANI, GN, AST GN, GP, AST GP, YST, NH, ANC

5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

The design control activities summary:

A risk assessment study was conducted to establish the performance of the DensiCHEK™ Plus with the VITEK®2 AST YS (yeast susceptibility) card for the drug Fluconazole. VITEK®2 AST YS (yeast susceptibility) card results obtained from fungal suspensions prepared using the DensiCHEK™ Plus were compared to the card results from suspensions prepared using the DensiCHEK™. The scope of the testing included two components Quality Control and Reproducibility.

The Quality Control testing was conducted at one external site. The appropriate quality control organisms, namely *Candida krusei* ATCC 6528 and *Candida parapsilosis* ATCC 22019 were tested against the drug Fluconazole. Testing yielded results that fell within acceptable range 100% of the time for both the DensiCHEK™ and DensiCHEK™ Plus.

Site	System/ Card	Organism	Drug	Accept. Range	DC+ Card 1	DC+ Card 2	DC+ Card 3	DC+ Card 4	DC Card 1	DC Card 2	DC Card 3	DC Card 4
1	VTK2/ AST-YS01	*C. krusei ATCC 6258*	Fluconazole	8-≥64	16	32	16	16	16	16	16	16
		C. parapsilosis ATCC 22019	Fluconazole	≤1-4	2	2	2	2	2	2	2	2

DC+ = DensiCHEK™ Plus DC = DensiCHEK™

The Reproducibility testing was conducted at two external sites and internally. A panel of 10 well characterized isolates was tested in triplicate for three days at the three sites. Testing yielded results that were in agreement with the mode greater than 95% of the time. More specifically, the overall best-case and worst-case reproducibility results were 99.6%, respectively.

6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.