

SPECIAL 510(k): Device Modification ODE Review Memorandum

Re: DOCUMENT NUMBER K033482- Dade Behring Inc.

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 :

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. - K020398
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 .
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**.
This change was for a software functionality change which would allow the MicroScan DMS Software (LabPro) to report rapid Ampicillin susceptible results for *Proteus mirabilis* but not intermediate or resistant results.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and K020398 Intended Use: For use with MicroScan rapid/S plus Panels read on the WalkAway® -S1 System or equivalent (upgraded WalkAway® -40 or WalkAway® -96). MicroScan® panels are designed for use in determining quantitative and/or qualitative antimicrobial agent susceptibility and/or identification to the species level of colonies, grown on solid media, or rapidly growing aerobic and facultative anaerobic gram-negative bacilli. (Enterobacteriaceae, glucose non-fermenters, and non-Enterobacteriaceae glucose fermenters)

Similarities		
Item	Device	Predicate
Intended Use	Same as above	Same as above
Inoculum	Inoculum density to 0.5 McFarland standard	Inoculum density to 0.5 McFarland standard
Incubation	<16 hours	< 16 hours
Panels	Dried ampicillin at 0.25-128 ug/mL	Dried ampicillin at 0.25-128 ug/mL
Specimen	Isolated colonies from culture used	Isolated colonies from culture used
Differences		
Item	Device	Predicate
Results	If rapid result is Intermediate or Resistant, "Confirm With Overnight Results" If rapid result is Susceptible, Report result.	Do Not Report Ampicillin Rapid Result and <i>Proteus mirabilis</i> . Results can be read manually after overnight incubation (16-20 hours).

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.

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.