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

To: THE FILE   **RE:**   DOCUMENT NUMBER   k062024

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.
    k990251 – Dimension Digitoxin Flex reagent cartridge
    k946153 – Dimension Digoxin Flex reagent cartridge
    k962819 - Dimension Gentamicin Flex reagent cartridge
    k032564 – Dimension N-acetylprocainamide Flex reagent cartridge
    k911056 – Dimension Phenytoin Flex reagent cartridge
    k862955 – Dimension Theophylline Flex reagent cartridge

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).

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 repackaging existing reagents.

    Comparison Information (similarities and differences) to applicant's legally marketed predicate

     device including, labeling, intended use, sample type, analytes, detection methods *and the number of tests per reagent pack. The Dimension Vista supports more tests per pack than the Dimension platform. This was accomplished by decreasing the reagent and sample volumes.*

4. 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.
        The sponsor conducted a Failure Mode and Effect Analysis (FEMA); this analysis did not identify any risks. An internal review identified the loss of precision due to a decrease in reagent volume and pipetting errors as the primary risks associated with this platform migration.
    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
        A comparison of the new device and predicate labeling indicates the reduction in reagent volume is proportionate to the reduction in sample volume. The final concentration of sample/reagent ratio in the test milieu is the same for the both devices.
    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.

5. 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 device.

_____   07/24/06
(Reviewer's Signature)   (Date)

Comments
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revised:8/1/03