

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

To: THE FILE

RE: DOCUMENT NUMBER K103805

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.

Transtube MW176 OT MD176 (K872213)

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.

The Medical Wire S-Transwab® products are substantially equivalent to the previously cleared device. The previously cleared and the modified devices are swab transport systems using Liquid Amies Medium as the transport medium. The previously cleared and the modified devices are identical in intended use and overall function

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 cleared device has a longer tube to hold the entire swab, with a push fit cap attached to the swab which forms a seal with the tube.
- The new device has a shorter, self-standing vial with screw cap. The swab shaft has a breakpoint to allow it to be snapped into the transport vial.
- The new device has been validated in conformity to CLSI M40-A

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

Item	Device: Sigma Transwab® MW176S & variants (K103805) Modified	Predicate: Transtube® MW176 & variants (K872213)
Similarities		
Intended Use	Transport medium is Liquid Amies.	Same
Test Method	The device is used to collect a specimen from patient for transport to a laboratory and analysis by microbiological methods.	Same
Device Type	Same	Same

Differences		
	<p>Medium is located at bottom of a small selfstanding cylindrical tube</p> <p>Swab is broken along shaft to fit easily within the tube of medium</p> <p>Unused tube of medium is closed with plastic screw cap</p> <p>Used tube of medium is closed by same plastic screw cap.</p> <p>Medium easily removed from tube by pipette for multiple processing.</p>	<p>Medium is located within a polyurethane sponge at base of non-rolling polypropylene tube</p> <p>Entire swab fits within swab tube, with bell cap holder serving double function as plug for tube</p> <p>Unused tube of medium fits is closed with plastic push fit plug</p> <p>Used tube of medium is plugged by the bell cap holder on the swab</p> <p>Long tube requires long pipette to remove used medium for processing</p>

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 Sigma Transwab®. The Sigma Transwab Risk Analysis is based on EN ISO 14971:2007. This risk analysis include; Energy hazards, Biological hazards, Potential Hazards of the patient and End User, Environmental hazards, Hazards related to the use of the device, Hazards arising from functional failure, maintenance and ageing. And Specific hazards pertinent to new design.

Validation studies were conducted at one external site.

Studies were conducted to evaluate the performance characteristics of the Medical Wire S-Transwab® in accordance with CLSI "Quality Control of Microbiological Transport Systems"; Approved Standard M40-A. Tests were performed to simulate transport at fridge temperature and room temperature. Data collected for the previously cleared device were used for the assignment of shelf life of 24 months, with satisfactory recoveries being observed in multiple batches for at least 30 months.

Quality control was performed using the CLSI Standard M40-A.

The Declaration of Conformity was 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.