

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

To: THE FILE

RE: DOCUMENT NUMBER K082661
Applicant: Princeton BioMeditech Corp.

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.
K983386/A001, BioStrep A; K971349, BioSign Strep A and K040708/A002, StatusFirst Strep A.
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).
Indications for use did not change.
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 change to the incubation time for the antigen extraction in the Strep A tests from the current 2-5 minutes to 1-2 minutes.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and test performance.

Features		Pre-amended devices k971349, k983386, k040708	Amended devices
Scientific principle and technology		Solid phase immuno-chromatographic assay	Same as pre-amended device
Intended use		To aid in the early diagnosis of Group A Streptococcal infection, <i>in vitro</i> qualitative test	Same as pre-amended device
Analyte		Group A streptococcus	Same as pre-amended device
Antibodies		Antibodies to group A streptococcus	Same as pre-amended device
Specimen collection		Throat swab	Same as pre-amended device
Extraction Reagent volume		4 drops of Reagent A and 4 drops of Reagent B	Same as pre-amended device
Extraction reagent concentration	A	2M sodium nitrite	Same as pre-amended device
	B	0.05M phosphoric acid	0.2M phosphoric acid
Incubation time for extraction of antigen		2 min	1 min
Result reading time after extracted sample application		5-10 min	Same as pre-amended device
Result reading method		Visual Reading	Same as pre-amended device
Sensitivity		Detects 1.5×10^5 CFU/mL	Same as pre-amended device
Manufacturer		Princeton BioMeditech Corp.	Same as pre-amended device

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 sponsor submitted all the Design Control studies. See attached reviewer's memo.

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.