SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K232669

B Applicant

Abbott Laboratories

C Proprietary and Established Names

TBI

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QAT	Class II	21 CFR 866.5830 - Brain trauma assessment test	IM - Immunology

II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter's own **CLASS II** device requiring 510(k). The following items are present and acceptable.

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)

2. Submitter's statement that the **INDICATIONS FOR USE/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 modification of the cleared TBI test for use on the ARCHITECT i1000SR System due to the identification during design evaluation of the potential for reagent carryover with 25-OH Vitamin D assay that may lead to elevated GFAP assay results. A limitation in the package insert for the TBI test for use on the ARCHITECT i1000SR System informs users of a potential risk for false positive TBI results for the GFAP assay when the TBI test is run after the 25-OH Vitamin D assay and provides actions to take to mitigate potential contamination after 25-OH Vitamin D assay testing.

4. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.

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.

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.