

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

To: THE FILE

RE: DOCUMENT NUMBER k053426

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. ELECSYS® Anti-Thyroglobulin (Anti-Tg) Antibody Test System (k020672)
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

1. Correct a typographical error of the source of the Anti-Tg antibodies in Cal 2 from human to sheep.
2. Change calibrator form from liquid to lyophilized.
3. Change the stability claims for calibrators to 6 weeks (2-8 °C) upon reconstitution.
4. Change the stability claims for all other reagents and controls to 6 weeks (2-8 °C) to harmonize to that of the calibrators.
5. Change the filling volume of the calibrators from 1.3 ml to 1.5 ml.
6. Change concentration of monoclonal anti-Tg antibodies (human) labeled with ruthenium complex from 0.52 mg/L to 0.62 mg/L.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, traceability/standardization, test principle, measuring range, and limitations:

Item	K020672 (Predicate)	Modified Device
Calibrators	Liquid	Lyophilized
Stability (Opened) Reagents (M, R1, R2) PC-A-Tg1, PC-A-Tg2	up to twelve weeks, 2-8 °C up to eight weeks, 2-8 °C	up to six weeks, 2-8 °C. six weeks, 2-8 °C
Reagent 2 (R2)	0.520 mg/L	0.620 mg/L
Cal2 source	Typographical error listed as human	Sheep
Package Insert		
Precautions and warnings		Avoid the formation of foam with all reagents and sample types (specimens, calibrators, and controls).
Specimen collection and preparation		The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in

Item	K020672 (Predicate)	Modified Device
		some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.
Calibration verification	Not necessary. The analyzer's software automatically checks the validity of the curve and draws attention to any deviations.	Deleted
Expected Values		Reference to brochure "Reference Intervals for Children and Adults" added
References		#5 added #9 (data on file at Roche) deleted
"Limited License" & "Limited Warranty"		Added

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. (See *"Risk Analysis Results," in Section IV, pg. 32-33.*)
 - 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. (See *"Summary of Risk Analysis," in Section IV, pg. 31.*)
 - c) A declaration of conformity (See *Section IV, pg. 34*) 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** and the **Indications for Use Enclosure.** (See *Section II, pg. 22-23 & Section III, pg. 25*)

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.