SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K200033

B Applicant

Instrumentation Laboratory Co.

C Proprietary and Established Names

HemosIL von Willebrand Factor Antigen

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GGP	Class II	21 CFR 864.7290 - Factor Deficiency Test	HE - Hematology

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 (HemosIL von Willebrand Factor Antigen, K992704).

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.

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 change was for a modified Rheumatoid Factor (RF) interference claim in the "Limitations/Interfering substances" section of the HemosIL von Willebrand Factor Antigen package insert from "the presence of Rheumatoid Factor may produce an overestimation of vWF:Ag results on ACL Family Systems" and "vWF:Ag results on ACL TOP Family and ACL TOP Family 50 Series are not affected by Rheumatoid Factor up to 750 IU/mL" to a new claim. The new claim states "vWF:Ag results on ACL Family Systems are not affected by Rheumatoid Factor up to 50 IU/mL" and "vWF:Ag results on ACL TOP Family and ACL TOP Family 50 Series are not affected by Rheumatoid Factor up to 50 IU/mL."

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.