

K925213

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510(k) Summary of Safety and Effectiveness Information
Stratus® Myoglobin Fluorometric Enzyme Immunoassay
December 27, 1996

Dade International Inc.
2173 N.W. 99th Avenue
Miami, FL 33172

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Trade or Proprietary Name: Stratus® Myoglobin Fluorometric Enzyme Immunoassay

Common or Usual Name: Myoglobin immunological test system

Classification Name: None

Registration Number: *Manufacturer*

Dade International Inc.
2173 N.W. 99th Avenue
Miami, FL 33172

1025506

(formerly at 9750 N.W. 25 Street, Miami, FL 33172)

Dade International Inc.
1851 Delaware Parkway
Miami, Florida 33125

1017272

The proposed Stratus® Myoglobin Fluorometric Enzyme Immunoassay is substantially equivalent in intended use and technological characteristics to the current Stratus® Myoglobin Fluorometric Enzyme Immunoassay, manufactured by Dade International Inc., Miami, FL, previously cleared under Document Control No., K922125/A. The proposed device is being modified to include heparinized plasma as a sample type.

During an in-house comparative performance study, 101 patient samples were analyzed in duplicate for both serum and heparinized plasma samples using the Stratus® Myoglobin Assay procedure. The correlation coefficient was calculated at 0.98 and the regression equation was $y = 0.94x + 7.09$, where y = plasma samples. The correlation coefficient and the regression equation were found to be acceptable.