

K904862

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**510(k) Summary of Safety and Effectiveness Information  
Stratus® Cardiac Troponin-I Fluorometric Enzyme Immunoassay and  
Stratus® Cardiac Troponin-I Calibrators  
December 3, 1996**

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

Contact Person: Radha Goolabsingh at 305-392-5621 or by facsimile at 305-392-5622.

**Trade or Proprietary Name:** Stratus® Cardiac Troponin-I Fluorometric Enzyme  
Immunoassay and Stratus® Cardiac Troponin-I Calibrators

**Common or Usual Name:** Troponin-I 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® Cardiac Troponin-I Fluorometric Enzyme Immunoassay and Stratus® Cardiac Troponin-I Calibrators is substantially equivalent in intended use and technological characteristics to the Stratus® Cardiac Troponin-I Fluorometric Enzyme Immunoassay and Stratus® Cardiac Troponin-I Calibrators, manufactured by Dade International Inc., Miami, FL, previously cleared under Document Control No., K951890. The proposed device is limited to modifications in the indications for use. The additional indication for use is to aid in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.