K962596

EXHIBIT 1

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510(K) Summary
Customed
Blood Collection Kit

SEP 27 1996

Submitter Information

Customed
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510(K) Summary Prepared By:

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Date 510(K) Summary Prepared: August 15, 1996

Trade or Proprietary Name: Customed Blood Collection Kit

Common Name: Venous Blood Specimen Collection Kit

Classification Name: Blood Specimen Collection devices, 21 CFR 862.1675

Identification of Legally Marketed Device to which the Submitter Claims Equivalence:

The Customed Blood Extraction kit is substantially equivalent in intended use, and kit contents as various blood collection kits legally marketed by Angiosystems, Inc. under K905464/A.

Description of the Subjected Devices:

The Customed Blood Collection Kits are an assembly of medical products within a pouch. The medical products are disposable, and single use. The primary purpose is for the convenience of the Healthcare professional. The trays are custom to the customer, and include a variety of medical devices that are legally marketed, are exempt, or are grandfathered. These components of the kit are commonly used for blood specimen collection and Customed is not claiming or causing new uses through the intended use of the kit.

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## Intended Use of the Subject Devices

The Customed Blood Collection Kits are intended to be used by Healthcare professions for venous blood specimen collection and transport, and is for In-Vitro Diagnostic Use only. The kit is used to prepare the skin for sampling, provide blood collection tubes and needles for the sampling procedure, and to cover the sampling site when the procedure is complete.

## Technical Characteristics of the Subject Device

The technological characteristics of the Customed Blood Collection kit and the predicate device are substantially eqivalent as supported by the comparison of similar significant features, components, and intended use.

No clinical evaluations were completed.