SAGE PRODUCTS INC K964168

16 510(k) Summary

MAR - 3 1997

Submitter Name	Karen Pinto, Regulatory Affairs Manager
Company Name	Sage Products Inc.
Street Address	815 Tek Drive, Crystal Lake, IL 60014
Contact Person	Karen Pinto, Regulatory Affairs Manager
Telephone of Contact Person	815-455-4700 ext. 1383
Fax of Contact Person	815-455-5599
Date of Summary Preparation	February 14, 1997
Device Name	
Trade or Proprietary Name	Procedure Specific Kits
Common Name	Convenience kits
Classification Name	Convenience kits have not been classified
K Number	K964168
Intended Use	Combinations of products for the convenience and personal protection of the end user from blood, body fluids and chemicals while conducting specific procedures. The kits will include disposable, single use items for blood, drug or chemical spill clean up, drug preparation and/or drug administration.

"Innovative health care products since 1971"

815 TEK DRIVE ▪ P.O. BOX 9693 ▪ CRYSTAL LAKE, IL 60014-9693
815-455-4700 ▪ 800-323-2220 ▪ FAX: 815-455-5599

SAGE PRODUCTS INC

16 510(k) Summary (Continued)

Description

Procedure Specific kits are non-sterile kits that bundle or package together combinations of products for the convenience of the user. This saves the end user the time and effort of retrieving the individual products each time a procedure is performed.

Kit components are purchased as released finished goods in finished package form. To assemble a kit, individual products are selected, sealed in a polybag or other suitable container, and labeled with a contents label. If the finished package form is more than one unit, Sage will remove the number of units specified for the kit being assembled. The item will be repackaged in the kit without compromising the integrity of the product. There is no reprocessing of any of the components that would compromise an original intended use or alter its safety or effectiveness.

Substantial Equivalence Comparison

Some items which are convenience packed into the procedure specific kits are medical devices. These devices are pre-amendment devices, devices exempt for pre-market notification or have been cleared per the pre-market notification process and have been found substantially equivalent to a predicate device.

The packaging of these commonly used devices will not affect the safety or effectiveness of the devices nor will the devices be marketed for a new or different indication for use.

"Innovative health care products since 1971"

815 TEK DRIVE ▪ P.O. BOX 9693 ▪ CRYSTAL LAKE, IL 60014-9693
815-455-4700 ▪ 800-323-2220 ▪ FAX: 815-455-5599