

The Keller Funnel®2 HOSPITAL BULLETIN

Keller Medical, Inc. is aware of the challenges of introducing new products within a hospital product registry. The following material was specifically compiled to help facilitate discussions that hospital product board review committees may conduct prior to approving the Keller Funnel 2 for purchase.

MANUFACTURER

Keller Medical, Inc.
1239 SE Indian Street, #112
Stuart, FL 34997
Telephone: 772-219-9993

Federal ID# 26-2093764

PRODUCT DESCRIPTION

KELLER FUNNEL®2 Catalog # HA-005
Contents: 5 sterile, individually packaged Keller
Funnels in a single shelf carton, with
Instructions for Use

PRICING

For pricing, please refer to current price list.

FDA REGISTRATION & PRODUCT LISTING INFORMATION

The Keller Funnel 2 is a Class I Exempt device and therefore does not require a 510(k) letter of clearance.

Proprietary Name:	Keller Funnel 2	
Classification Name:	KIT, SURGICAL INSTRUMENT, DISPOSABLE	
Product Code: KDD	Device Class: 1	Regulation Number: 878.4800
Medical Specialty:	General & Plastic Surgery	
Registered Establishment Name:	Keller Medical, Inc.	
Registration Number:	3007802878	Status: Active
Owner/Operator:	Keller Medical, Inc.	Owner/Operator Number: 10029751
Establishment Operations:	Manufacturer; Specification Developer	
Establishment:	Keller Medical, Inc. 1239 S.E. Indian Street, #112 Stuart, FL 34997	

NO-LATEX STATEMENT: The Keller Funnel 2 is not made with natural rubber latex. The Keller Funnel 2 is made of polymeric vinyl and is coated with a hydrophilic coating.

PRODUCT REIMBURSEMENT: Keller Medical, Inc. is not aware of any reimbursement codes for use in cosmetic procedures such as primary breast augmentation or revision surgeries. Each hospital billing department can provide guidance on which codes may be applicable for reconstructions for congenital deformities, breast-cancer related mastectomies, or severe trauma.

For questions related to administration, orders or accounting, please contact the company at:

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