K974347

Baldur

Baldur Systems Corporation
3423 Investment Blvd. • Suite 12 • Hayward, CA 94545-3822
Phone: (510) 732-9715 Fax: (510) 732-9716

FEB 10 1998

510 (k) SUMMARY
[As required by 807.92(a)]

Date of application: November 17, 1997

Applicant's and manufacturers name and street address:

Applicant's name: Baldur Systems Corporation
3423 Investment Blvd., Ste. 12
Hayward, CA 94545

Contact person: David Hu, Ph.D., President

Telephone and FAX numbers of applicant:

Tel: 510-732-9715 Fax: 510-732-9716

Manufacturer's names: a). Ying Chun Surgical Dressing Factory
28 Koutai Road
Taizhou Shi 225300, China
Contact person: Liu, Yu-Lin, General Manager
Telephone and fax numbers: Tel: 523-833-9243 Fax: 523-633-9243

b). Kanglin Healthcare Ltd. Co.
1, East Economic Development District
Taizhou, Jiangsu, China
Contact person: Zhu, Hai-Ling, General Manager
Telephone and fax number: Tel: 5241-230-466 Fax: 5241-227-671

Trade name: "Baldur" Non-Sterile Cotton Sponges

Common name: Cotton Gauze

Classification name: Gauze Sponge (per 21 CFR 880.6250)

Legally marketed device: Class I gauze sponge 79EFQ

Description of device: Class I gauze sponge 79EFQ

Intended use of device: A gauze is used to wipe off blood and fluids from the patient's mouth or skin.

Technological Characteristics: "Baldur" gauze sponges meet the USP/BP standards.

Performance data: The performance data is shown in Table 1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 1998

David Hu, Ph.D.
President
Baldur Systems Corporation
3423 Investment Boulevard, Suite 12
Hayward, California 94545-3822

Re: K974347
Trade Name: "Baldur" Non-Sterile Cotton Sponges
Regulatory Class: Unclassified
Product Code: EFQ
Dated: November 17, 1997
Received: November 19, 1997

Dear Dr. Hu:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for

devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K974347

Device Name: Gauze sponges

Indications For Use:

A gauze is used to wipe off blood and fluids from a patient's mouth or skin.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974347

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-9