THE TOOLS

| New Products |

■ **Single Step™**, a breast biopsy device for the diagnosis of breast cancer, (SenoRx Inc., Aliso Viejo, Calif.) has received 510(k) clearance from the FDA. The novel proprietary device is indicated for both lesion localization and diagnostic tissue sampling with partial or complete removal of an imaged abnormality.


K-Shield

■ **K-Shield** (Kawasumi Laboratories America, Inc., Tampa, Fla.), a needle safety device to protect oncology clinicians from Huber needle stick injuries incurred while removing needles from subcutaneous ports, has received FDA 510(k) clearance for marketing. K-Shield provides a convenient way to dispose of Huber needles, does not cause the patient discomfort, and does not cause any needle movement during infusions.

■ **Acuity™** (Varian Medical Systems, Inc., Palo Alto, Calif.), a new medical imaging product that integrates planning, simulation, and verification radiation oncology software, has received 510(k) clearance from the FDA. Intended to accelerate the adoption of IMRT, Acuity supports ultra-precise radiotherapy by dynamically tracking tumor motion during the simulation and verification process.

■ The FDA granted clearance for **ACIS®**, an automated cellular imaging system (ChromaVision Medical Systems, San Juan Capistrano, Calif.), to market the use of the system to perform two tests that help the cancer care team determine an appropriate course of treatment for patients with breast cancer.


ACIS

■ **Proprietary radiofrequency (RF) ablation technology** (RITA Medical Systems, Inc., Mountain View, Calif.) has received 510(k) clearance from the FDA to market its RF ablation technology to treat pain for bone metastases. In March 2000, RITA received FDA clearance to use its RF ablation technology to treat unresectable liver lesions.

■ **Lodox** (Lodox Systems Ltd., Sandton, South Africa), a full-body, low-dosage X-ray diagnostic imaging system, has been granted marketing approval from the FDA.

Lodox uses a quick, high-resolution, low-dose X-ray beam to detect concealed gemstones, and has been remodeled for medical applications. Lodox can scan the entire body in approximately 13 seconds, and the image can be manipulated and enhanced to reveal soft tissues.

■ **The Responder® IV system** (Rauland-Borg Corp., Skokie, Ill.) integrates wireless phones and pocket pagers with more traditional nurse call bed stations, staff stations, and consoles. Staff members can choose the means of communication that will best fit their situation and work style. The system is fully customizable to individual department requirements.

For more information on the Responder IV system, contact Rauland-Borg Corporation at 800-752-7725 or visit: *www.rauland.com*.

■ The FDA approved adding information about the **Vysis PathVysion fluorescence in situ hybridization (FISH) test** (Abbott Laboratories, Abbott Park, Ill.) to the label for Herceptin, a monoclonal antibody treatment for women with metastatic breast cancer.

One of the first examples of genomic disease management, PathVysion is used to detect HER-2/neu gene status, which identifies women who are potential candidates for Herceptin.

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| On the Internet |

■ **www.net-learning.com**
NetLearning provides computer-based learning and learning management systems for the health care market. The web site offers more than 1,000 courses on topics including coding, JCAHO/OSHA compliance, and continuing education, as well as the ability to customize courseware to the needs of individual health care systems. The e-learning interface allows users to complete coursework on their own schedules and at their own pace, take computer-based learning (CBL) courses, and take examinations for both CBL and instructor-led classes.

■ **www.healthstream.com**
HealthStream's Healthcare Learning Center (HLC) provides training and education, and courses can be customized to fit specific budgetary and programmatic needs. The HLC can reduce the cost of education and training by allowing health care professionals to access online education units from work or home.

HealthStream's Leadership Practices Survey (LPS) is a web-based evaluation of current leadership behavior administered and collected over the Internet and designed to provide information on management strengths and weaknesses.

■ **www.medscape.com/cmecenterdirectory**
Medscape's CME Center offers self-study activities in 27 medical specialty areas, and automatically tracks ongoing credits with its CME Tracker. MedScape has CMEs for pharmacists and nurses as well. Medical experts also provide expanded coverage of presentations from major medical conferences.

CMEs are offered in a variety of forms—including multi-media presentations with audio, slides, and transcripts—and can be downloaded and printed. Tests and exams are taken and submitted online.

THE TOOLS

DRUGS

■ The Oncologic Drugs Advisory Committee (ODAC) of the FDA recommended that AstraZeneca's drug Iressa® (ZD1839 also known as gefitinib) be granted accelerated FDA approval for third-line treatment of advanced non-small cell lung cancer, following at least two chemotherapy agents. Iressa, a selective epidermal growth factor receptor (EGFR) inhibitor, is a daily pill designed to shrink tumors without producing the toxic effects of chemotherapy. If approved, Iressa will be made available within two weeks of the final FDA decision.

■ A new derivative of thalidomide (ENMD0995) has received FDA Orphan Drug designation for the treatment of patients with multiple myeloma. A product of EntreMed, ENMD0995 is a small molecule analog of thalidomide with improved angiogenesis inhibitor activity that in animal models does not show evidence of the toxic side effects reported for thalidomide. ENMD0995 may also be a candidate for the treatment of B-cell tumors, some lymphomas, as well as some solid tumors.

FDA Orphan Drug designation encourages the development of therapeutics to treat diseases affecting fewer than 200,000 Americans by providing tax credits and marketing exclusivity incentives to the company.

■ AstraZeneca has received FDA approval to use Arimidex (anastrozole) for the adjuvant treatment of hormone-receptor positive early breast cancer in postmenopausal women.

Arimidex received the FDA's accelerated approval based on findings from the ATAC (Arimidex, Tamoxifen, Alone or in Combination) cancer treatment study, which found that Arimidex produced a statistically significant improvement in recurrence-free survival compared with tamoxifen.

■ Atrix Laboratories, Inc., has started marketing Eligard 22.5 mg (leuprolide acetate suspension for injection), a new proprietary product for the palliative treatment of advanced prostate cancer. Eligard 22.5 mg uses Atrix's drug delivery system, Atrigel, to deliver leuprolide acetate over a three-month period.

This product complements Eligard 7.5 mg (leuprolide acetate suspension for injection), also developed by Atrix, which was launched in late May 2002 and releases leuprolide acetate over one month.

In April 2002, Atrix submitted a New Drug Application for Eligard 30 mg, a four-month sustained release product, which is currently under FDA review.

■ The FDA has granted Orphan Drug status to Canada's AEterna Laboratories, Inc., for a compound extracted from the cartilage of sharks to be used in the treatment of renal cell carcinoma. The FDA Orphan Drug designation entitles AEterna to receive seven-year exclusive marketing rights for that indication if the extract is approved.

Fast Facts

HMOs' and Health Insurers' 2001 Profitability by State

The nation's HMOs and health insurers reported a 25 percent increase in profits for 2001, earning $4.1 billion for the year, compared to $3.1 billion in 2000.

STATE	Net Profit (Loss)
Alabama	$53,325,553
Arizona	36,384,469
Arkansas	40,356,785
California	611,187,552
Colorado	40,875,419
Connecticut	123,951,671
Delaware	11,176,294
District of Columbia	54,334,488
Florida	60,200,963
Georgia	99,535,426
Hawaii	14,506,406
Idaho	3,906,000
Illinois	404,810,650
Indiana	419,984,468
Iowa	28,716,552
Kansas	(53,063,955)
Kentucky	13,633,739
Louisiana	29,130,499
Maine	14,476,106
Maryland	46,698,556
Massachusetts	194,956,710
Michigan	57,297,381
Minnesota	64,970,609
Mississippi	18,739,450
Missouri	21,208,651
Montana	6,190,204
Nebraska	21,786,804
Nevada	(5,415,578)
New Hampshire	44,787,532
New Jersey	178,286,692
New Mexico	19,197,144
New York	702,101,791
North Carolina	58,373,717
North Dakota	23,883,557
Ohio	127,961,628
Oklahoma	(2,811,975)
Oregon	68,181,722
Pennsylvania	384,244,890
Puerto Rico	24,182,885
Rhode Island	86,420,242
South Carolina	66,749,724
South Dakota	(1,694,862)
Tennessee	73,312,842
Texas	(477,077,247)
Utah	13,902,338
Vermont	6,541,687
Virginia	75,916,597
Washington	142,871,554
West Virginia	12,886,353
Wisconsin	15,067,580
Wyoming	4,060,419
Industry Totals	$4,084,208,682

Note: Data for Alaska were not reported.
Source: Weiss Ratings, Inc., September 2002

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