

4 FDCR

AN 14G47019 8811.

TI In Brief.

SO GRAY-SHEET, November 21, 1988, PAGE 23-24.

DT 881121.

TX 1 of 21

Siemens: Acquires the Eureka x-ray tube division of Litton Industries for an undisclosed amount. Located in Chicago, Illinois, Eureka employs 150 in the manufacture of x-ray tubes and accessories. Siemens President Robert MacKinnon said that "no management changes are contemplated at this time and Eureka will continue to operate as an independent OEM supplier to equipment manufacturers and service organizations".....

2 of 21

Mediq: Michael Sandler, formerly a partner at accounting firm Touche Ross, is named chief financial officer at Mediq. Sandler replaces Lionel Felzer, who remains as a senior vice president, treasurer and director....

3 of 21

Circon: Santa Barbara, California surgical device company received Oct. 17 reg letter from FDA for GMP violations in the manufacture of the AUR-65 flexible uretherpyloscope and electrohydraulic lithotripter. FDA also says that Circon failed to submit medical device adverse reaction reports in at least three instances when Circon products may have caused serious injury in patients....

682817176

4 of 21

Ingene: Santa Monica, California company receives patent protection from the European Patent Office for protein preparations used to promote bone growth. Called osteonic factors, possible applications include strengthening the implantation of orthopedic, dental and plastic surgery devices in bone. Ingene is developing the products under a \$4.5 mil. joint venture with Biomet....

5 of 21

Infratech: "Problem-solving" firm for pharmaceutical, medical device and biotechnology companies is founded by Jeffrey Wigand, PhD, former president of Biosonics and vice president and director at Merck Diagnostic Systems. Specializing in services to the Japanese market, the Vorrhees, New Jersey company will provide assistance on start up, management, strategic planning, manufacturing and marketing....

6 of 21

ICN Pharmaceuticals: Costa Mesa, California company receives 510(k) clearance from FDA to market a clinical laboratory test which allows testing for marijuana and cocaine from a single patient sample, and a reagent kit for morphine....

7 of 21

Infrasonics: Files 510(k) for a new infant ventilator system, the Star Sync. "The new design is for babies who either 'fight' breathing on regular ventilators, have changing breathing cycles, or as an aid in weaning," Infrasonics says....

8 of 21

Applied Biomedical Sciences: Long Beach, California biomaterials firm elects Revlon Exec VP Eustace Fotiu to its board of directors....

9 of 21

Zinnanti Surgical Instruments: Chatsworth, California firm has failed to validate its design and manufacturing procedures, FDA says in an Oct. 12 regulatory letter. The agency says that Zinnanti's Hystero-Kit for hysterosalpingography, hydrotubation and uterine insemination are not in compliance with good manufacturing practices. The letter notes that Zinnanti has a 510(k) application pending for the hydrotubation and uterine insemination applications....

10 of 21

Pharmacia: Preparing to launch automated DNA synthesis system, the Gene Assembler Plus. The system will be marketed worldwide....

11 of 21

Gen-Probe: U.S. Patent Office has allowed claims in a Gen-Probe patent "relative to the detection of infectious organisms based upon the uniqueness of their genetic make-up," Gen-Probe said Oct. 27. "An allowance of claims normally precedes issuance of a patent by four to six months"....

12 of 21

Home Diagnostics Inc.: Eatontown, Pennsylvania company receives 510(k) clearance from FDA to market its LipoScan rapid blood cholesterol test. The LipoScan consists of a disposable test strip which produces color changes to indicate cholesterol levels when a drop of blood is added. Home Diagnostics will begin distributing the test to physicians in January through wholesalers in Florida, Illinois, Michigan, Wisconsin and California....

13 of 21

Home-use IVDs: FDA makes available a draft document of "points to consider

682817177

regarding labeling and premarket submissions'' for home-use in vitro diagnostics (''The Gray Sheet'' July 6, 1987, p. 3). The agency is accepting comments on the draft until Feb. 14, 1989. For single copies, write the Dockets Management Branch (HFA-305), FDA, Room 4-62, 5600 Fishers Lane, Rockville, Maryland, 20857....

14 of 21

Gut suture reclassification: Davis & Geck and Ethicon petition FDA to reconsider its final order reclassifying gut sutures from Class III ''premarket approval'' to Class II ''performance standards'' (''The Gray Sheet'' Oct. 10, p. 9). The filing of the petitions is the last administrative option open to the firms in their effort to keep the transitional devices in Class III. A spokesperson for Ethicon would not comment on whether the company would initiate legal action against FDA if the petitions are denied....

15 of 21

LEP Scientific: Surrey, England-based company introduces the Prem blood analysis system for HIV testing. According to LEP, the Prem recognizes the unique DNA ''fingerprint'' of the AIDS virus, allowing nearly 100% accurate results in hours. Priced at approximately \$11,000, the Prem will initially be marketed in the United Kingdom and Third World countries....

16 of 21

Incstar: Signs letter of intent to acquire Minneapolis, Minnesota-based Techne, a holding company for Research and Diagnostic Systems of Minneapolis and Hycel S.A. of Rennes, France, developers of hematology products. Incstar will swap 1 mil. shares of preferred stock for outstanding Techne shares. The stock can be converted into Incstar common shares, which are currently trading at \$7. Techne had sales of about \$12 mil. in FY 1988 (year ended June 30)....

17 of 21

Molecular Biosystems: FDA gives firm permission to expand clinical study of its Alburnex ultrasound imaging agent to Phase III multi-center trials, Molecular announces Nov. 3. The company expects to file a new drug application for Alburnex in about a year....

18 of 21

Mallinckrodt: Introduces the new Softouch angioplasty catheter and Clear Shot balloon inflation device at the American Heart Association's Nov. 14-17 meeting in Washington, D.C. The Softouch has an internal diameter of .079 inches, ''the largest available in an eight French guiding catheter,'' which ''permits the use of up to 25% more contrast media,'' Mallinckrodt says....

19 of 21

The Cooper Companies: Elects Ralph Thurman to its board of directors. Currently senior vice president at Rorer, Thurman's responsibilities include mergers and acquisitions, public affairs, management information systems and human resources. Thurman becomes the ninth member of the Cooper board....

20 of 21

Allergan Hydron: FDA and firm enter into consent decree which enjoins the company from selling the OfficeTint system for tinting contact lenses. The decree also requires that the firm complete retrieval of sold devices by the end of December. In 1987, FDA filed a complaint against International Hydron, before it was purchased by SmithKline Beckman's Allergan subsidiary, charging that the system caused adulteration of the contact lenses it tinted. Hydron discontinued sales of the OfficeTint in January

682817178

and has been retrieving the products since that time....

21 of 21

Wesley-Jessen: Opens new \$3.2 mil. plant in Cidra, Puerto Rico for the manufacture of contact lenses. The plant will employ 450 in the production of tinted prescription and cosmetic lenses....

682817179