

1. FDA MEDICAL EQUIPMENT RECALLS AND ALERTS. The following recalls are reported in accordance with AFMILL 2-95, page CE-4, and should be treated as directed modifications in accordance with that AFMILL and AFI 41-201, Chapter 2, Section D. If you possess any of these items and have not received recall notification, you should contact the manufacturer for recall instructions. Suspension is only required for Class I items.
(FOM-P, Capt Paul J. Toth, DSN 343-7445)

CLASS I RECALLS: None.

CLASS II RECALLS:

6515 NS

MDC 13182

PRODUCT

Pulmonary Function Analyzers

Software for Pulmonary Function Testing System:

- a) BreezePF v3.8 Software, Catalog No. 147536-003;
- b) BreezePF v3.8A Software, Catalog No. 147570-003.

Recall #Z-450/451-0.

CODE

None.

MANUFACTURER

Medical Graphics Corporation, St. Paul, Minnesota.

RECALLED BY

Manufacturer, by bulletin on January 8, 2000. Firm-initiated field correction ongoing.

DISTRIBUTION

Nationwide and international.

QUANTITY

657 software disks were distributed.

REASON

An anomaly has been discovered in the software that can cause confusion on the selection of which FEV1/FVC ratio is selected for diagnostic reporting. The problem only occurs when using the Quality Review or Bronchial Provocation Review software to select best composite efforts.

[] None Present

[] Action Taken _____

6530 NS

MDC 16298

PRODUCT

Clinical Chemistry Analyzer, Automated

Alycon Analyzers, automated chemistry analyzers for in-vitro diagnostic use: a) Alycon Analyzer 300; b) Alycon Analyzer 300i. Recall #Z-462/463-0.

CODE

All codes.

MANUFACTURER

Abbott Laboratories, Inc., Irving, Texas.

RECALLED BY

Manufacturer, by letter dated January 13, 2000. Firm-initiated recall ongoing.

DISTRIBUTION

Nationwide and Puerto Rico.

QUANTITY

535 analyzers distributed in the United States from 5/1/98 to 12/1/99.

REASON

Software program errors cause incorrect association between patient and the patient results.

[] None Present

[] Action Taken _____

2. DRUG/SUPPLY PRODUCT RECALLS AND MEDICAL INFORMATION. The Food and Drug Administration (FDA) advises that the drug products listed below were recalled by the manufacturers or distributors concerned. The FDA has classified these recalls as follows:

CLASS I: A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.

CLASS II: A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

CLASS III: A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Most of these items are nonstandard, and the possibility exists that medical activities may have purchased them locally. There is also a possibility that some of these items have NSNs assigned and may have been reported in earlier Q.A. messages. Activities having quantities of these items on hand will immediately suspend the materiel from issue and use. **CONUS** activities will contact the nearest office of the respective manufacturer or distributor for disposition instructions. **OVERSEAS** activities will report quantities suspended to AFMLO/FOM-P no later than **2 Jun 00** for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DSCP purchase order number, contract number, and stock record account number (SRAN). (FOM-P), **Bonnie Phillips DSN (343-4170)**

CLASS I RECALLS: None

CLASS II RECALLS:

NSN PRODUCT	6505 Nonstandard Corneas. Recall #B-454-0. Graft Identification Numbers: 0264-93-01, 0264-93-02, 0283-94-01, 0283-94-02, 0056-96-01, 0056-96-02, 0104-96-01, 0104-96-02, 0677-97-01, 0677-97-02, 0360-98-01, 0360-98-02, 0376-98-01, 0688-98-01, 0098-99-01, 0098-99-02, 0103-99-01, 0103-99-02, 0198-99-01, 0198-99-02, 0221-99-01, 0221-99-02, 0225-99-01, 0225-99-02, 0238-99-01, 0267-99-01, 0267-99-02, 0018-00-01, 0018-00-02.
MANUFACTURER	Lions Medical Eye Bank and Research Center of Eastern Virginia, Norfolk, Virginia.
RECALLED BY	Manufacturer, by telephone and/or letters on February 22, 1999, April 22, 1999, June 24, 1999, August 3, 1999, January 5 and 11, 2000. Firm-initiated recall ongoing.
DISTRIBUTION	Virginia, Illinois, Florida, South Carolina, Missouri, Georgia, North Carolina, South Dakota, Texas, Minnesota, Ohio, Washington state, Nebraska, California, and international.
QUANTITY	29 corneas.
REASON	Corneas collected from donors who tested repeatedly reactive for either the antibody to the Hepatitis B core antigen (anti-HBC), HbsAg or anti-HTLV-I/II, or HIV-p-24 antigen which was not confirmable by PCR.
	<input type="checkbox"/> None Present
	<input type="checkbox"/> Action Taken _____

NSN PRODUCT	6515 Nonstandard Implantable Cardiovascular Defibrillators, used to detect ventricular arrhythmias and deliver therapy for the detected arrhythmia. The devices are designed to treat ventricular fibrillation, ventricular tachycardia, and bradycardia: a) GEM II VR Single Chamber Implantable defibrillator, Model No. 7229CX; b) GEM II DR Dual Chamber Implantable Cardiovascular Defibrillator, Model No. 7273. Recall #Z-452/453-0.
CODE	<p>Serial Numbers:</p> <p>United States Distribution:</p> <p>Model 7229CX: PJJ200000H, PJJ200001H, PJJ200002H, PJJ200021H, PJJ200024H, PJJ200025H, PJJ200026H, PJJ200027H - PJJ200034H, PJJ200035H, PJJ200036H, PJJ200037H, PJJ200039H and PJJ200040H.</p> <p>Model 7273: PJK200004H, PJK200005H, PJK200010H, JK200015H, PJK200071H - PJK200078H, PJK200108H, PJK200110H, JK200115H, PJK200116H, PJK200119H, PJK200121H, PJK200122H, PJK200124H - PJK200126H, PJK200138H, PJK200139H, PJK200141H, PJK200144H, PJK200147H, PJK200152H, PJK200154H - JK200158H, PJK200160H, PJK200161H, PJK200164H, PJK200167H, PJK200169H - PJK200172H, PJK200178H, PJK200190H - PJK200201H, PJK200203H, PJK200206H, PJK200207H, PJK200211H, PJK200212H, PJK200215H, PJK200217H, PJK200218H, PJK200220H, PJK200221H, PJK200224H, PJK200229H, PJK200268H, PJK200272H, PJK200274H, PJK200279H, PJK200283H - PJK200288H, PJK200294H, JK200296H, PJK200298H - PJK200300H, PJK200302H, PJK200303H, JK200307H, PJK200309H, PJK200311H, PJK200312H, PJK200315H, PJK200317H, PJK200319H, PJK200320H, PJK200323H, PJK200324H, PJK200326H - PJK200328H, PJK200335H, PJK200336H, PJK200338H, PJK200339H, PJK200341H, PJK200345H, PJK200348H, PJK200353H, PJK200354H - PJK200356H, PJK200360H, PJK200364H, JK200369H, PJK200371H, PJK200372H, PJK200381H - PJK200384H, JK200389H, PJK200391H, PJK200395H, PJK200398H, PJK200407H, PJK200408H, PJK200412H, PJK200414H, PJK200415H, PJK200421H, PJK200425H, PJK200427H, PJK200429H - PJK200433H, PJK200435H, JK200436H, PJK200438H, PJK200440H, PJK200441H, PJK200443H, PJK200444H, PJK200450H, PJK200451H, PJK200455H, PJK200458H - JK200461H, PJK200466H, PJK200469H - PJK200482H, PJK200484H, PJK200486H - PJK200489H, PJK200491H, PJK200493H - PJK200495H, PJK200497H, PJK200500H, PJK200502H - PJK200504H, JK200506H, PJK200508H, PJK200509H, PJK200512H - PJK200514H, JK200516H, PJK200518H, PJK200519H, PJK200521H, PJK200523H, PJK200524H, PJK200526H - PJK200537H, PJK200540H - PJK200542H, JK200544H - PJK200547H, PJK200549H, PJK200551H, PJK200555H, PJK200556H, PJK200558H, PJK200559H, PJK200565H - JK200568H, PJK200571H, PJK200572H, PJK200574H, PJK200576H, PJK200577H, PJK200580H, PJK200597H - PJK200599H, PJK200602H, JK200603H, PJK200609H, PJK200610H, PJK200616H, PJK200617H, PJK200618H - PJK200623H, PJK200626H, PJK200628H, JK200629H, PJK200630H, PJK200636H, PJK200656H - PJK200659H, PJK200660H - JK200668H, PJK200670H - PJK200678H, PJK200680H, PJK200682H - PJK200684H, PJK200686H, PJK200688H - PJK200700H, PJK200702H, PJK200703H, PJK200705H - PJK200710H, PJK200712H, PJK200713H, PJK200715H, PJK200716H, PJK200718H, PJK200721H, PJK200724H, PJK200726H - PJK200728H, PJK200730H, PJK200732H - PJK200735H, PJK200738H, PJK200741H, PJK200743H, PJK200745H - PJK200747H, PJK200757H - PJK200765H, PJK200768H - PJK200774H, PJK200776H, PJK200777H, PJK200779H - JK200781H, PJK200783H,</p>

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Distribution to Australia:

Model 7273: PJK200319S, PJK200320S, PJK200738S, PJK200740S, PJK201842H, PJK201909H, PJK201912H, PJK201916H, PJK201927H, PJK200399S, PJK200412S, and PJK200419S.

Distribution to Canada:

Model 7273: PJK200174H, PJK200214H, PJK200305S, PJK200310S, PJK200322S, PJK200323S, PJK200346S, PJK200520S, PJK200521S, PJK200522S, PJK200524S, PJK200526S, PJK200528S, PJK200606H, PJK200607H, PJK200611H, PJK200696S, PJK200743S, PJK200762S, PJK200768S, PJK200853H, PJK200857H, PJK200989H, PJK201815H, PJK201834H, PJK201835H, PJK201837H, PJK201838H, PJK201883H, PJK201922H, PJK202178H, PJK202209H, PJK200415S and PJK200424S.

Distribution to Europe:

Model 7229Cx: PJJ200038S, PJJ200040S, PJJ200045S, PJJ200077R, PJJ200078R, PJJ200079R, PJJ200080R, PJJ200082R - PJJ200088R, PJJ200090R - PJJ200092R, PJJ200094R - PJJ200098R, PJJ200100R - PJJ200104R, PJJ200106R, PJJ200107R, PJJ200109R, PJJ200110R - PJJ200116R, PJJ200118R - PJJ200120R, PJJ200124R - PJJ200126R, PJJ200128R - PJJ200133R, PJJ200135R - JJ200138R, PJJ200162R, PJJ200164R - PJJ200166R, PJJ200168R, PJJ200170R - PJJ200172R, Model 7273: PJK100462R, PJK100467R, PJK100471R, PJK100476, PPK100478R, PJK100545R - PJK100552R, PJK100554R, PJK100556R, PJK100558R, PJK100592R, PJK100593R, JK100595R, PJK100600R, PJK100603R, PJK100606R - PJK100608R, JK100612R - PJK100619R, PJK100625R - PJK100629R, PJK100632R, PJK100636R, PJK100640R, PJK100642R, PJK100643R, PJK100646R, PJK100651R - PJK100653R, PJK100656R, PJK100657R, PJK100661R, PJK100663R, PJK100665R, PJK100669R, PJK100670R, PJK100672R, PJK100675R, PJK100677R, PJK100679R, PJK100681R, PJK100682R, PJK100684R, PJK100685R, PJK100687R - PJK100694R, PJK100718R - PJK100726R, PJK100729R - PJK100735R, PJK100737R, PJK200022R, PJK200023R, PJK200029R, PJK200031R, PJK200032R, PJK200036R - PJK200038R, PJK200040R, PJK200064S, PJK200066S, PJK200067S - PJK200070S, PJK200108S, PJK200109S, PJK200115S, PJK200124S, PJK200126S, PJK200131S - PJK200134S, PJK200136S, PJK200173H, PJK200175H, PJK200204H, PJK200242S, PJK200254S, PJK200266H, PJK200267H, PJK200285S, PJK200287S - PJK200291S, PJK200293S, PJK200294S, PJK200296S, PJK200298S, PJK200300S, PJK200302S, PJK200303S, PJK200313S, PJK200317S, PJK200344S, PJK200365S, PJK200367S, PJK200373S - PJK200376S, PJK200378S - PJK200380S, PJK200382S - PJK200388S, PJK200390S - PJK200393S, PJK200395S - PJK200398S, PJK200400S - PJK200404S, PJK200407S, PJK200409S, PJK200411S, PJK200413S, PJK200414S, PJK200416S - PJK200418S, PJK200420S - PJK200422S, PJK200423S, PJK200425S, PJK200427S, PJK200428S, PJK200513S - PJK200515S, PJK200519S, PJK200525H, PJK200529S, PJK200532S, PJK200533S, PJK200538H, PJK200539H, PJK200597S - PJK200600S, PJK200603S - PJK200608S, PJK200610S - PJK200617S, PJK200619S, PJK200620S, PJK200622S, PJK200623S, PJK200624H, PJK200625H, PJK200625S, PJK200627H, PJK200627S, PJK200632S, PJK200634S, PJK200693S, PJK200695S, PJK200697S - PJK200699S, PJK200701S, PJK200702S, PJK200704S, PJK200706S - PJK200709S, PJK200712S, PJK200713S, PJK200715S - PJK200720S, PJK200723S, PJK200725S, PJK200728S - PJK200731S, PJK200731H, PJK200732S, PJK200733S, PJK200735S, PJK200736S, PJK200739H, PJK200739S, PJK200741S, PJK200742H, PJK200742S, PJK200746S, PJK200748H, PJK200748S, PJK200750H - PJK200752H, PJK200756H, PJK200757S, PJK200767S, PJK200772S, PJK200786H, PJK200797H, PJK200799H,

PJK200801H, PJK200803H, PJK200804H, PJK200806H, PJK200823H, PJK200824H, PJK200827H - PJK200831H, PJK200833H, PJK200835H - PJK200839H, PJK200881H, PJK200933H, PJK200934H, PJK200936H, PJK200938H, PJK200941H, PJK200943H, PJK200944H, PJK201065H, PJK201070H, PJK201078H, PJK201081H, PJK201138H, PJK201139H, PJK201145H, PJK201150H, PJK201152H, PJK201153H, PJK201154H, PJK201156H, PJK201157H, PJK201160H, PJK201164H, PJK201171H, PJK201175H, PJK201300H, PJK201306H, PJK201309H, PJK201311H, PJK201313H, PJK201319H, PJK201335H, PJK201442H, PJK201470H, PJK201471H, PJK201492H, PJK201493H, PJK201500H, PJK201501H, PJK201503H, PJK201705H, PJK201706H, PJK201738H, PJK201808H, PJK201811H, PJK201816H, PJK201819H, PJK201821H, PJK201824H - PJK201827H, PJK201830H - PJK201833H, PJK201840H, PJK201947H, PJK201950H, PJK201961H, PJK201966H and PJK201968H.

Distribution to Hong Kong:

Model 7273: PJK200249S, PJK200286S, PJK200679H, PJK200909H, PJK200945H, PJK201473H, PJK201820, PJK202206H, and PJK202207H. Medtronic, Inc., Minneapolis, Minnesota; Medtronic Med Rel, Inc., Humacao, Puerto Rico; Medtronic, Switzerland Manufacturing Operations, Tolochenaz, Switzerland.

MANUFACTURER

RECALLED BY

Medtronic, Inc., Minneapolis, Minnesota, by letter dated February 11, 2000. Firm-initiated recall ongoing.

Nationwide and international.

1,628 defibrillators were distributed from December 1998 to November 1999.

A fracture of a soldered connection in the devices could result in loss of telemetry and device output.

[] None Present

[] Action Taken _____

NSN
PRODUCT

6515 Nonstandard

Various Heart Valves and Annuloplasty Rings:

a) St. Jude Medical Masters Series Rotatable Aortic Mechanical Heart Valve with Silzone Coating, Cuff Type, models:

Standard Polyester: 19AS-601, 21AS-601, 23AS-601, 25AS-601, 27AS-601, 29AS-601, 31AS-601.

Expanded Polyester: 19AECS-602, 21AECS-602, 23AECS-602, 25AECS-602, 27AECS-602, 29AECS-602, 31AECS-602.

Hemodynamic Plus Cuff: 17AHPS-605, 19AHPS-605, 21AHPS-605, 23AHPS-605, 25AHPS-605, 27AHPS-605.

Expanded HP Cuff: 17AEHPS-605, 19AEHPS-605, 21AEHPS-605, 23AEHPS-605, 25AEHPS-605, 27AEHPS-605.

b) St. Jude Medical Masters Series Rotatable Mitral Mechanical Heart Valve with Silzone Coating, Cuff Type, models:

Standard Expanded Polyester: 19MS-601, 21MS-601, 23MS-601, 25MS-601, 27MS-601, 29MS-601, 31MS-601, 33MS-601, 35MS-601, 37MS-601.

Expanded Polyester: 19MECS-602, 21MECS-602, 23MECS-602, 25MECS-602, 27MECS-602, 29MECS-602, 31MECS-602, 33MECS-602.

Hemodynamic Plus: 17MHPS-605, 19MHPS-605, 21MHPS-605, 23MHPS-605 25MHPS-605, 27MHPS-605.

Expanded HP Cuff: 17MEHPS-605, 19MEHPS-605, 21MEHPS-605,

23MEHPS-605, 25MEHPS-605, 27MEPHS-605.
c) St. Jude Medical Regent Rotatable Aortic Mechanical Heart Valve with Standard Polyester Cuff Having Silzone Coating, models: 17-AG-701, 19-AG-701, 21-AG-701, 23-AG-701, 25-AG-701, 27-AG-701, 29-AG-701;
d) St. Jude Medical Regent Rotatable Aortic Mechanical Heart Valve with Flex/Polyester Cuff Having Silzone Coating, models: 17AGF706, 19AGF706, 21AGF706, 23AGF706, 25AGF706, 27AGF706, 29AGF706;
e) St. Jude Medical Seguin Annuloplasty Ring for Mitral Valve Repair with Silzone Coating, models: SARS-M24, SARS-M26, SARS-M28, SARS-M30, SARS-M32, SARS-M34, SARS-M36, SARS-M38, SARS-M40;
f) St. Jude Medical Tailor Annuloplasty Ring with Silzone Coating, models: TAR-25, TAR-27, TAR-29, TAR-31, TAR-33, TAR-35;
g) St. Jude Medical Epic Porcine Aortic Bioprosthetic Heart Valve, models: ELS-21A, ELS-23A, ELS-25A, ELS-27A, ELS-29A, ELS-31A;
h) St. Jude Medical Epic Porcine Mitral Bioprosthetic Heart Valve, models: ELS-21M, ELS-23M, ELS-25M, ELS-27M, ELS-29M, ELS-31M. Recall #Z-454/461-0.

CODE All serial numbers of SMJ valves and annuloplasty rings with Silizone silver coating.
MANUFACTURER St. Jude Medical, Inc., St. Paul, Minnesota.
RECALLED BY Manufacturer, by letters on January 21 and 26, 2000. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 47,283 mechanical heart valves, 963 Epic Porcine valves, and 3,083 annuloplasty rings were distributed.
REASON There is a statistically significant higher rate of paravalvular leaks with the silver ion (Silzone) coated sewing cuffs leading to valve explants.

[] None Present
[] Action Taken _____

NSN 6515 Nonstandard
PRODUCT Ventak Prism Automatic Implantable Cardioverter Defibrillator, VR Models 1850 and 1855, and DR Models 1851 and 1856. These cardioverter defibrillators are intended for use in patients who are at high risk of sudden cardiac death due to ventricular arrhythmias.
Recall #Z-469/470-0.
CODE Model 1850 Serial Numbers:
100027, 100028 - 100030, 100032, 100033, 100036, and 100039.
Model 1851 Serial Numbers: 300129 - 300137, 300139 - 300143, 300156 - 300158, 300160 - 300162, 300164 - 300166, 300168 - 300171, 300173 - 300175, 300177, 300178, 300181 - 300190, 300192, 300194, 300195, 300197, 300199, 300201, 300204, 300205, 300207 - 300209, 300213, 300216, 300218, 300222, 300224 - 300226, 300228, 300238, 300239, 300243, 300244, 300246 - 300249, 300251, 300252, 300254, 300255, 300261, 300262, 300264, 300266 - 300273, 300277, 300278, 300281, 300283, 300286, 300287, 300290, 300294, 300295, 300298, 300301 - 300306, 300308, 300311 - 300313, 300316, 300321, 300323 - 300326, 300330, 300331, 300336, 300339, 300341, 300343, 300344, 300348 - 300350, 300362, 300363, 300365, 300366, 300376 - 300379, 300381, 300385, 300386, 300388, 300393 - 300399, 300402 - 300405, 300407, 300408, 300410, 300413 - 300416, 300418, 300419, 300421, 300422, 300424, 300425, 300427, 300428, 300429, 300430, 300432, 300437, 300439, 300442, 300448,

300449, 300452 - 300455, 300458, 300460, 300462 - 300469, 300472 - 300478, 300480, 300481, 300484 - 300492, 300494, 300498, 300500 - 300504, 300506 - 300509, 300511, 300512, 300515 - 300517, 300519, 300521, 300525, 300527, 300528, 300533 - 300536, 300542, 300548, 300550, 300551, 300553 - 300555, 300558, 300560, 300562, 300563, 300565 - 300567, 300570 - 300576, 300578 - 300583, 300619 - 300621, 300627, 300628, 300631, 300640, 300643, 300653, 300654, 300656,
300658, 300674, 300676, 300683, 300691, 300695, 300702, 300714, 300719, 300720, 300737, 300738, 300740, 300743, 300744, 300745, 300747, 300748, 300750 - 300752, 300773 - 300775, 300789, 300844, 300845, 300846, 300847, 300852, 300853, 300858, 300862, 300871, 300942, 300963, 301012, 301025, 301204, 301272, 301273, 301274, 301276, 301290, 301339, 301364, 301369, 301376, 301377, 301379, 301381, 301382, 301397, 301406, 301409 - 301411, 301417, 301418, 301420 - 301424, 301426, 301431 - 301433, 301445, 301452, 301454, 301459, 301482 - 301484, 301519, 301544, 301545, 301595, 301608, 301612, 301633, and 301694.

Model 1855 Serial Numbers: 500014, 500015, 500016, 500017, and 500018.

Model 1856 Serial Numbers: 600027, 600028, 600029, 600030, and 600031.

Guidant Corporation, St. Paul, Minnesota.

Manufacturer, by memorandum on February 13, 2000, and by letter dated February 14, 2000, followed by visit. Firm-initiated recall ongoing.

Nationwide, Australia, Canada, Israel, New Zealand, Europe.

364 units.

Defect in an integrated circuit that can result in device failure.

[] None Present

[] Action Taken _____

MANUFACTURER
RECALLED BY

DISTRIBUTION
QUANTITY
REASON

NSN
PRODUCT

CODE

MANUFACTURER
RECALLED BY

DISTRIBUTION
QUANTITY
REASON

NSN
PRODUCT

6550 Nonstandard

Elecsys Troponin T Immunoassay for the in-vitro quantitative determination of troponin T in human serum and plasma:

a) Catalog #2017423, Elecsys Tronponin T STAT Immunoassay, 100 Tests;

b) Catalog 2017644, Elecsys Tronponin T Immunoassay, 100 test.

Recall #Z-426/427-0.

a) Lot Numbers: 19862701 EXP 12-31-2000 and 19829401

EXP 03-31-2000; b) 19864201 EXP 12-31-2000.

Roche Diagnostics Corporation, Germany.

Roche Diagnostics Corporation, Indianapolis, Indiana, by letter dated December 13, 1999. Firm-initiated field correction ongoing.

Nationwide.

Approximately 13,000 units.

The devices may give test results lower than actual troponin T results when heparinized plasma samples are used.

[] None Present

[] Action Taken _____

6550 Nonstandard

Strep A Tests, an in-vitro diagnostic medical device intended for the qualitative detection of group "A" streptococcal antigen from throat swabs or confirmation of presumptive group "A" streptococcal colonies

CODE recovered from culture:
 a) OSOM Strep A Test (Brand for Wyntek);
 b) Signify Strep A Test (Brand for Abbott Labs.);
 c) ACCEAVA Strep A Component-Test Sticks (Brand for Biostar).
 Recall #Z-444/446-0.
 a) Product No. 141, Lot Nos. 7301, 7310; and Product No. 998,
 Lot No. 7310-10;
 b) Product No. 99-0347, Lot Nos. 59947M200, 59948M200, 59949M200,
 59951M200, 61473M200 through 61476M200
 c) Catalog No. ACCGAS-C Lot Nos. 017294, 017297, 017301, 017306,
 017313, 017315; and Catalog No. ACCGAS10-C, Lot No. 017301-10.
 Wyntek Diagnostics, Inc., San Diego, California.
MANUFACTURER RECALLED BY
DISTRIBUTION
QUANTITY
 OSOM (50 count) 1,565
 OSOM (10 count) 33
 SIGNIFY 20,435
 ACCEAVA (50 count) 13,695
 ACCEAVA (10 count) 250 were distributed.
REASON
 The devices may sporadically show color trace with the negative control, producing a false positive reading on an external negative control.

 None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Blood Collection Reservoirs, indicated for use with patients undergoing cardiopulmonary bypass or autotransfusion procedures:
 a) Blood Collection Reservoirs, Models EL240 and EL2120
 b) Cardiotomy Reservoirs, Models EL400, EL402, and EL404.
 Recall #Z-447/448-0.
CODE All lots.
MANUFACTURER RECALLED BY
DISTRIBUTION Nationwide and international.
QUANTITY 380,477 units were distributed; firm estimated that 5,000 units remained on market at time of recall initiation.
REASON There are holes in some of the sterile packages.

 None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT COBAS Integra Ammonia (NH3L) Cassettes, contains an in-vitro diagnostic reagent intended for use on COBAS Integra 400 and 700 for the quantitative determination of the ammonia concentration in plasma: a)

CODE Catalog #0766682; b) Catalog #0737453.
MANUFACTURER Recall #Z-464/465-0.
RECALLED BY Lot Numbers B2434 EXP 4/00 and B2635 EXP 5/00.
Roche Diagnostics GmbH, Mannheim, Germany.
DISTRIBUTION Roche Diagnostics Corporation, Indianapolis, Indiana, by letter on
QUANTITY February 9, 2000. Firm-initiated recall ongoing.
REASON Nationwide.
Undetermined.
Lithium heparin plasma may give erratic results compared to EDTA plasma
using the ammonia assay.

[] None Present
[] Action Taken _____

NSN 7610 Nonstandard
PRODUCT Literature for BioSorb FX 2.0/2.4 Bioabsorbable Fixation System.
Recall #Z-449-0.
CODE Lot #1939.
MANUFACTURER Bionx Implants Ltd., Tampere, Finland.
RECALLED BY Bionx Implants, Inc., Blue Bell, Pennsylvania. On September 20, 1999,
the recalling firm ceased further distribution of literature and any
copies remaining in sales representatives' stock were removed and any
copies remaining in distributors' stock will be returned.
DISTRIBUTION Canada, Australia, Latin America.
QUANTITY 2,550 units were distributed.
REASON Device is labeled for unintended use. Firm's sales literature misbrands
the device for mandibular indications.

[] None Present
[] Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Voltaren(r)-XR Extended Release Tablets (Diclofenac Sodium), 100 mg, in
100 count bottles, Rx used for chronic therapy of osteoarthritis and
rheumatoid arthritis, and for the treatment of ankylosing spondylitis.
NDC 0028-0205-01.
Recall #D-251-0.
CODE Lot # 104A7322 EXP 9/01.
MANUFACTURER Novartis Pharma AG, Stein, Switzerland (bulk).
RECALLED BY Novartis Pharmaceuticals Corporation, Suffern, New York
(repacker/labeler), by fax on December 29, 1999.
DISTRIBUTION Firm-initiated recall ongoing.
QUANTITY Nationwide.
REASON 9,750 bottles were distributed.
Dissolution failure (release rate) at 4 and 8 hour time period(s).

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT VDRL (Venteral Disease Research Laboratory) Test Kit-5.0 mL
ampoule, slide test provides both qualitative and
semi-quantitative results. Recall #Z-466-0.
CODE Part #600902, Lot #VDRLA-107 EXP 10/01.
MANUFACTURER Avanti Polar Lipids, Inc., Alabaster, Alabama.
RECALLED BY Manufacturer, by verbal communication, followed by letter on
February 1, 2000. Firm-initiated recall ongoing.
DISTRIBUTION Minnesota.
QUANTITY 2 test kits.were distributed.
REASON The device was labeled with an incorrect expiration date.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Antacid Calcium Regular Strength, 500 mg, OTC in 150 tablet bottles.
Recall #D-250-0.
CODE NDC 62211-024-02.
MANUFACTURER Lot 9D02410 EXP 05/2001.
RECALLED BY Lot 9K02413 EXP 10/2002.
DISTRIBUTION A&Z Pharmaceutical, Inc., Hauppauge, New York.
QUANTITY Manufacturer, by letters on November 4-5, 1999, and December 8, 1999.
Firm-initiated recall ongoing.
REASON Nationwide.
10,336 bottles of lot 9D02410 and 3,510 bottles of lot 9K02413
were distributed.
Mislabeling - Supplement facts labeling panel incorrectly lists
calcium level per serving at 4000 mg.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Decadron(r) Phosphate Injection (Dexamethasone Sodium Phosphate),
USP, 4 mg per 5 ml injection, Rx. NDC #0006-7268-03. Recall #D-253-0.
CODE Lot Numbers: 0580H, 0874H, 1476H, 0051J, 0329J, and 1577H.
MANUFACTURER Merck and Company, West Point, Pennsylvania.
RECALLED BY Manufacturer, by letter dated February 17, 2000.
DISTRIBUTION Firm-initiated recall ongoing.
QUANTITY Nationwide and Canada.
REASON 51,691 vials were distributed.
Product degradation at 12-month stability - single degradate.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Corneas. Recall #B-455-0.
CODE Graft Identification Numbers: 0571-97-01, 0571-97-02,

MANUFACTURER 0019-99-01, 0019-99-02, 0071-99-01, 0071-99-02, 0286-99-01, 0286-99-02.
Lions Medical Eye Bank and Research Center of Eastern Virginia,
Norfolk, Virginia.

RECALLED BY Manufacturer, by telephone and/or letters on February 22, 1999,
April 22, 1999, June 24, 1999, August 3, 1999, January 5 and 11, 2000.
Firm-initiated recall ongoing.

DISTRIBUTION Virginia, Illinois, Florida, South Carolina, Missouri, Georgia,
North Carolina, South Dakota, Texas, Minnesota, Ohio, Washington
state, Nebraska, California, and international.

QUANTITY 7 corneas.

REASON Corneas collected from donors who tested repeatedly reactive for either
the antibody to the Hepatitis B core antigen (anti-HBC), HbsAg or anti-
HTLV-I/II, or HIV-p-24 antigen which was not confirmable by PCR.

[] None Present

[] Action Taken _____

NSN 6520 Nonstandard

PRODUCT Steri-Oss, HL Threaded Implant, HA Coated, endosseous dental
implant: Part #5612HL, 5 mm x 12 mm; b) Part #4610HL,
4.5 mm x 10 mm. Recall #Z-467/468-0.

CODE Lot Numbers: a) 302453 EXP 10/04; b) 302457 EXP 10/04.
MANUFACTURER Nobel Biocare USA, Inc., Yorba Linda, California.
RECALLED BY Manufacturer, by letter on January 19, 2000.
Firm-initiated recall ongoing.

DISTRIBUTION Nationwide, Japan, Argentina, South Korea, Hong Kong.
QUANTITY a) 144 units; b) 26 units were distributed.
REASON Healing screws were mismatched between the two sizes
during production assembly.

[] None Present

[] Action Taken _____

NSN 6550 Nonstandard

PRODUCT Light Diagnostics Simulfluor HS/VZV immunofluorescence Assay, intended
for the simultaneous detection and identification of herpes Simplex
(HSV) 1 and 2 and Varicella-Zoster Virus (VZV) from patients with
vesicular, oral, or skin lesions, using direct specimens and culture
confirmation. Recall #Z-443-0.

CODE Catalog #3295, Lot #19102679.
MANUFACTURER Chemicon International, Inc., Temecula, California.
RECALLED BY Light Diagnostics, Div. Chemicon International, Inc., Temecula,
California, by letter on or before February 16, 2000.
Firm-initiated field correction ongoing.

DISTRIBUTION Arizona, California, Connecticut, Florida, Kansas, Maryland,

QUANTITY

REASON

12 kits were distributed.

Labeling error - The primary reagent, labeled in part "SimuFlour
HSV/VZV ***EXP 12/00" should bear the expiration date "02/01:
as indicated on the box end label.

[] None Present

[] Action Taken _____
