September 29, 1995, of the approval of the application.

DATES: Petitions for administrative review by January 16, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Christopher M. Sloan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243.

SUPPLEMENTARY INFORMATION: On February 3, 1992, Datascope Corp., Montvale, NJ 07645, submitted to CDRH an application for premarket approval of the VasoSeal Vascular Hemostasis Device. The device is a vascular hemostasis device and is indicated for use in reducing time to hemostasis at the femoral arterial puncture site in patients who have undergone diagnostic angiography or percutaneous transluminal coronary angioplasty (PTCA) procedures using an 8 French or smaller procedural sheath. The VasoSeal VHD is also indicated for use in PTCA patients when immediate sheath removal is desired.

On May 8, 1995, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application.

On September 29, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before January 16, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: November 29, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95–30610 Filed 12–14–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95M–0396]

Karl Storz Endoscopy-America, Inc.; Premarket Approval of Storz Modulith Lithotripter, Model SL20

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Karl Storz Endoscopy-America, Inc., Kennesaw, GA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Storz Modulith Lithotripter, Model SL20. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of February 17, 1995, of the approval of the application.

DATES: Petitions for administrative review by January 16, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John H. Baxley, Center for Devices and Radiological Health (HFZ–472), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION: On November 24, 1993, Karl Storz Endoscopy-America, Inc., Kennesaw, GA 30144, submitted to CDRH an application for premarket approval of the Storz Modulith Lithotripter, Model SL20. The device is an extracorporeal shock wave lithotripter and is indicated for use in the noninvasive fragmentation of urinary calculi in the kidney and upper ureter.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On February 17, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's

action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before January 16, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: December 4, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95–30611 Filed 12–14–95; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[ORD–082–N]

New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act

October 1995.

AGENCY: Health Care Financing Administration (HCFA, HHS).

ACTION: Notice.

SUMMARY: This notice lists new proposals for Medicaid demonstration projects submitted to the Department of Health and Human Services during the month of October 1995 under the authority of section 1115 of the Social Security Act. This notice also lists proposals that were approved, disapproved, pending, or withdrawn during this time period. (This notice can be accessed on the Internet at HTTP://WWW.SSA.GOV/HCFA/HCFAHP2.HTML.)

COMMENTS: We will accept written comments on these proposals. We will, if feasible, acknowledge receipt of all comments, but we will not provide written responses to comments. We will, however, neither approve nor disapprove any new proposal for at least 30 days after the date of this notice to allow time to receive and consider comments. Direct comments as indicated below.

ADDRESSES: Mail correspondence to: Susan Anderson, Office of Research and Demonstrations, Health Care Financing Administration, Mail Stop C3–11–07, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Susan Anderson, (410) 786–3996.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 1115 of the Social Security Act (the Act), the Department of Health and Human Services (HHS) may consider and approve research and demonstration proposals with a broad range of policy objectives. These demonstrations can lead to improvements in achieving the purposes of the Act.

In exercising her discretionary authority, the Secretary has developed a number of policies and procedures for reviewing proposals. On September 27, 1994, we published a notice in the Federal Register (59 FR 49249) that specified (1) the principles that we ordinarily will consider when approving or disapproving demonstration projects under the authority in section 1115(a) of the Act; (2) the procedures we expect States to use in involving the public in the development of proposed demonstration projects under section 1115; and (3) the procedures we ordinarily will follow in reviewing demonstration proposals. We are committed to a thorough and expeditious review of State requests to conduct such demonstrations.

As part of our procedures, we publish a notice in the Federal Register with a monthly listing of all new submissions, pending proposals, approvals, disapprovals, and withdrawn proposals. Proposals submitted in response to a grant solicitation or other competitive process are reported as received during the month that such grant or bid is awarded, so as to prevent interference with the awards process.

II. Listing of New, Pending, Approved, and Withdrawn Proposals for the Month of October 1995

A. Comprehensive Health Reform Programs

1. New Proposals

No new proposals were received during the month of October.

2. Pending Proposals

Demonstration Title/State: Better Access for You (BAY) Health Plan Demonstration—Alabama.

Description: Alabama proposes to create a mandatory managed care delivery system in Mobile County for non-institutionalized Medicaid beneficiaries and an expansion population of low-income women and children. The network, called the Bay Health Network, would be administered by the PrimeHealth Organization, which is owned by the University of South Alabama Foundation. The State also proposes to expand family planning benefits for pregnant women whose income is less than 133 percent of the Federal poverty level.

Date Received: July 10, 1995.

State Contact: Vicki Huff, Director, Managed Care Division, Alabama Medicaid Agency, P.O. Box 5624, Montgomery, AL 36103–5624, (334) 242–5011.

Federal Project Officer: Maria Boulmetis, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: Arizona Health Care Cost Containment System (AHCCCS)—Arizona.

Description: Arizona proposes to expand eligibility under its current section 1115 AHCCCS program to individuals with incomes up to 100 percent of the Federal poverty level.

Date Received: March 17, 1995

State Contact: Mabel Chen, M.D., Director, Arizona Health Care Cost Containment System, 801 East Jefferson, Phoenix, AZ 85034, (602) 271–4422.

Federal Project Officer: Joan Peterson, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Demonstration Title/State: The Georgia Behavioral Health Plan—Georgia.

Description: Georgia proposes to provide behavioral health services under a managed care system through a