States participating in the marriage and divorce components of the Vital Statistics Cooperative Program (VSCP) will no longer be obtained. This change is being made to prioritize programs in a period of tightened resource constraints.

DATES: Written comments regarding these changes in the collection of marriage and divorce data must be received on or before January 15, 1996.

ADDRESSES: Written comments can be sent to the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, Attention: FR Response, Division of Vital Statistics, Room 840, 6525 Belcrest Road, Hyattsville, MD 20782.

FOR FURTHER INFORMATION CONTACT: Mary Anne Freedman, Director, Division of Vital Statistics, NCHS, CDC, telephone (301) 436–8951, ext. 112.

SUPPLEMENTARY INFORMATION: Viewed at either the individual level or the population level, marital status is a key variable in health, demographic, and policy research. As a result, data on current marital status and on change in marital status have been collected through a variety of Federal surveys and data systems. Among these systems are health surveys conducted by NCHS, the Current Population Survey conducted by the U.S. Bureau of the Census, and the records-based vital registration system conducted as a cooperative venture (the VSCP) between NCHS and the States. Within the VSCP, current marital status data are collected from birth certificates in the birth registration system, resulting, for example, in data on out-of-wedlock births. Marital status is also collected from death certificates in the death registration system. Data on change in marital status are obtained from marriage and divorce certificates.

NCHS plans to discontinue payments to the States and other vital registration areas for the collection of detailed data from marriage and divorce certificates, but will continue to request counts of marriages performed and divorces granted from all vital registration areas of the U.S. All other NCHS efforts to collect marital status information, including marital status for mothers on birth certificates, will continue.

NCHS data systems are continually being reviewed in light of resource constraints to assure that efforts are focused on the highest priority data needs. At a time when policy issues related to families are of great interest, NCHS has exercised caution to assure that data systems will be available to support monitoring and research interests in key priority areas. Over the last year, NCHS has systematically reviewed the availability and uses of detailed data on marriages and divorces. This review has led to the conclusion that the data most needed for setting policy (e.g., information on family formation, out-of-wedlock births, children living in single parent families) can be obtained through other sources, such as the birth registration system, other NCHS surveys, and the Current Population Survey.

The discontinuation of collection of detailed data from marriage and divorce certificates will result in a loss of data to researchers who currently rely on this data source for information on annual changes in the collective marriage and divorce behavior of the population, including trends and differentials in the propensity to marry, to divorce, and to remarry after divorce or widowhood. However, much of this information is available on a five year cycle from the June Marital History Supplement of the Current Population Survey.

Long-standing concerns about the completeness and quality of detailed marriage and divorce data from the VSCP were an important consideration in reaching the conclusion to discontinue payments to the States. Although the United States Government has collected marriage and divorce data through various methods since 1867, it was not until 1957 that a formal Registration Area was created for reporting detailed marriage data to NCHS; a similar Registration Area was created for divorces in 1958. These Registration Areas include States with adequate programs for collecting marriage and divorce statistics and which meet specific registration and reporting criteria for participation. More recently, NCHS has included marriage and divorce statistics in the VSCP, a contractual arrangement by which NCHS provides support to the State vital statistics programs and through which NCHS receives vital statistics data for analysis and dissemination at the national level.

Working with State vital registration offices and with various users of marriage and divorce data, NCHS has established standard certificates of marriage and divorce. These certificates contain selected data items about marriages and divorces, and certain of these items are required for admission to the registration areas. Due to variation in State laws on registration of marriage and divorce, not all States obtain these basic required items, and not all States have central registration facilities for marriages or divorces or both. At present, 41 States, the District of Columbia, Puerto Rico, and the Virgin Islands participate in the Marriage Registration Area and 31 States, the District of Columbia, and the Virgin Islands participate in the Divorce Registration Area. Detailed data are currently obtained from relatively small systematic samples of marriage and divorce records for these Areas. Although this system has been in place for many years, it has never been completed. Detailed data represent approximately 77 percent of marriages in the nation and 49 percent of divorces. For this reason, in addition to the detailed data, NCHS obtains counts of the number of marriages performed and the number of divorces granted from all States, the District of Columbia, Puerto Rico, and the Virgin Islands.

Fiscal constraints on State vital statistics programs have put stress on state-level quality assurance programs. As a result, in addition to the problem of coverage completeness, the quality of detailed marriage and divorce data has deteriorated. This deterioration is reflected mostly by the fact that, in some States, the response rates for certain key variables have fallen well below the minimum level acceptable to NCHS.

These coverage and quality concerns, the lack of identified resources to upgrade the system, and the availability of marital status data for high-priority needs from other sources have led NCHS, in consultation with data users, to conclude that resources currently devoted to the marriage and divorce component of the VSCP should be redirected to other priority uses.

Dated: December 8, 1995.

Claire V. Broome,

Deputy Director, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–30566 Filed 12–14–95; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 95M–0394]

Datascope Corp.; Premarket Approval of the VasoSeal Vascular Hemostasis Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Datascope Corp., Montvale, NJ, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the VasoSeal Vascular Hemostasis Device (VHD). FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of

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