Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices, Att. A Interagency Agreement, Att. B Criteria for Catergorization of Investigational Devices, & Att. C - List #D95-2 (blue book memo) (Text Only)

September 15, 1995 (D95-2)

IDE Guidance Memorandum #95-2

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

Office of Device Evaluation (HFZ-400)

Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices

ODE Review Staff

Purpose

The purpose of this memorandum is to establish procedures for fulfilling FDA's responsibilities as defined in the FDA/HCFA Interagency Agreement (IA) pertaining to the reimbursement of investigational devices.

Background

According to the statute governing the Medicare program (Section 1862 (a)(1)(A) of the Social Securities Act), the Health Care Financing Administration (HCFA) is permitted to reimburse for medical services and products that are deemed "reasonable and necessary" for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member. The Medicare program has historically interpreted the statutory terms "reasonable and necessary" to mean that a service or medical device must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. For Medicare coverage purposes, the term "experimental" has been used synonymously with the term "investigational." Therefore, with rare exception, an FDA-approved Investigational Device Exemption (IDE) application served as an indication that the device was not "reasonable and necessary" within the meaning of the Medicare program. Thus, Medicare coverage was denied for devices which were under an IDE and had not yet received premarket notification clearance and or premarket approval.

There is increasing recognition, however, that there are devices which are refinements of existing technologies or replications of existing technologies made by other manufacturers. Many of these devices are under an FDA-approved IDE as a means of gathering the scientific information needed for FDA to establish the safety and effectiveness of

that particular device, even though there is evidence that the device type can be safe and effective. Such devices could be viewed as "reasonable and necessary" by Medicare and thus be reimbursed if it were possible to identify these devices to HCFA.

On September 8, 1995, FDA and HCFA entered into an Interagency Agreement (See Attachment A) pursuant to which FDA agreed to institute a procedure for providing certain information to HCFA to aid in its reimbursement decisions. The information supplied to HCFA will be used in determining whether sufficient information exists concerning the safety and effectiveness of the investigational device to permit reimbursement under the Medicare program. Specifically, FDA will inform HCFA whether the clinical evaluation of an investigational device falls into one of two categories.

Those investigations involving innovative devices believed to be in Class III for which "absolute risk" of the device type has not been established (i.e., initial questions of safety and effectiveness have not been resolved and thus FDA is unsure whether the device type can be safe and effective) will be assigned to Category A. Devices believed to be in Classes I or II or devices believed to be in Class III where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved) will be assigned to Category B. Thus, Category B includes those device types known to be safe and effective because, for example, other manufacturers have obtained FDA approval/clearance for that device type. The precise criteria to be used by FDA in assigning IDEs to these reimbursement categories are set forth in the Interagency Agreement.

This interagency effort is an important initiative which will significantly impact both patient care and the development of new medical technology. By expanding the Medicare coverage policy to include certain investigational devices, Medicare beneficiaries will be assured greater access to the latest advancement in medical technology. In addition, the revision of the reimbursement policy to include investigational devices may help to improve the quality of clinical studies by ensuring that the Medicare patient population is included in the investigations and thus the devices are being tested on the appropriate patient population. Finally, it is anticipated that this change in policy will help to facilitate patient enrollment into

clinical trials. Implementation of FDA's responsibilities as defined in the Interagency Agreement will help attain these important goals.

Procedures

Below, the procedures to be used by ODE staff in order to fulfill FDA's responsibilities in the Interagency Agreement are described. Implementation of the IA will involve two phases. In phase I, all IDE applications that are either approved, conditionally approved, or deemed approved (unless deemed approved and immediately withdrawn) by September 15, 1995 will be assigned to one of the two reimbursement categories as described in the Interagency Agreement. Phase II of the process will begin on September 18, 1995. On this date, each reviewing division, as a routine part of the IDE review process, will assume responsibility for implementing the reimbursement categorization process for all IDEs that are received on or after that date. Each of these phases is discussed in detail below.

A. Phase I: Categorization of Approved IDEs

Using the criteria defined in the attachment of the Interagency Agreement, the divisions will be responsible for categorizing all IDEs which are approved ("full", conditional, or deemed) by September 15, 1995. A special training session will be conducted by ODE senior management and the IDE staff during which guidance on the categorization determination process will be provided to division supervisors (branch chiefs and associate/deputy division directors).

In most instances, it will be possible to categorize the investigational device based on data available in the IDE database; however, in some instances, it may be necessary to refer to the actual IDE application as well as information regarding similar marketed devices. It is anticipated that the vast majority of devices will be assigned to Category B (i.e., Non-experimental/Investigational). The data on reimbursement categorization will be compiled and forwarded to HCFA on or before November 1, 1995. Therefore, the categorization of all IDEs approved by September 15, 1995 must be completed and forwarded to the IDE staff no later than October 6, 1995.

The IDE staff will provide the divisions with a list of all IDE applications which must be categorized. This will include only those

IDEs in the database which are approved. IDEs which have been terminated will be considered exempt from this IA agreement and thus will not be assigned to a reimbursement category. The IDE staff will also provide ODE's reviewing divisions with a standardized form to allow the information to be captured in a uniform fashion. IDE staff consultation and concurrence is required for any IDE application which is assigned to Category A (i.e., Experimental). (The boilerplate checklist (Document H-1 on the LAN) which identifies the rationale for this categorization determination must be signed-off by both division management and the IDE staff. Also see Attachment B)

In order to make this information publicly available, the Division of Small Manufacturers Assistance (DSMA) will post on its electronic docket a list of the approved IDEs (IDE numbers only) and the corresponding reimbursement category.

B. Phase II: IDEs Approved after September 15, 1995

On September 18, 1995, the divisions will become responsible for determining the reimbursement categorization for those IDEs which are approved, conditionally approved, or deemed approved (unless deemed approved and immediately withdrawn). As previously noted, it is anticipated that in most instances categorization will be possible on the basis of a quick review of the division's records and the IDE database. As discussed above, for those cases where an IDE is assigned to Category A, the branch chief must contact the IDE staff prior to issuing the approval letter or otherwise notifying the sponsor or HCFA of this categorization decision. The IDE staff will review the decision and notify the division of its concurrence.

IDE boilerplate approval letters ("full", conditional, and deemed approved) for original IDEs and amendments will be modified as follows:

1. The reference block will be modified to include not only the IDE number and the name of the device but also the proposed indication for use for the device as stated in the clinical protocol and the HCFA Reimbursement Category: A (or B).
2. HCFA will be added to the distribution list at the bottom of all such letters. The Document Mail Center (DMC) will be responsible for mailing copies of these approval letters to HCFA.
3. An enclosure entitled, "Procedures to Request Re-evaluation of

Categorization Decisions" must be included in the approval letters when a Category A determination is made.

In order to create a written record of the basis for each categorization decision, reviewers must complete the checklist provided by the IDE staff (See Attachment B or document H-1 on the LAN). By using this checklist, the criterion which served as the basis for the categorization decision of the investigational device will be included in the IDE file as the checklist must be attached to the last page of the review memo. The categorization determination (category and reason code) must also be recorded on the tracking sheets for all original IDEs and amendments which are approved. (If this information is not included on the tracking sheet, the DMC will not be able to log the IDE out of the tracking system.) The DMC will be responsible for entering this information into the IDE database when the IDE is logged out of the tracking system.

The Office of Systems and Management has modified the IDE database to capture the reimbursement category and reason code assigned to each approved IDE. Such modifications will permit both searching of the IDE database and the generation of reports based on this criteria.

C. Changes in IDE Status

In the event that the approval of an IDE application is withdrawn, it is imperative that HCFA be apprised of this fact as soon as possible. Therefore, if after consultation with the IDE staff, the decision is made to withdraw approval of the IDE application, the reviewing division will be responsible for FAXing a copy of the final order which withdraws approval of the IDE to HCFA at the same time that the sponsor is notified of the withdrawal of approval. (See IDE boilerplate letter G-30A for the name of the HCFA contact person and FAX number to which this information should be forwarded.) HCFA should not be notified of proposed withdrawal letters as these may not lead to the final order.

D. Confidentiality of Categorization Determination

As provided for under 21 CFR 812.38(a), all information pertaining to an IDE, regardless of its status, is confidential. This includes the categorization determination. Thus, except for the information which

DSMA will post on its electronic docket, information regarding the reimbursement categorization decision should only be released to the sponsor of the IDE and to HCFA. Therefore, the divisions should refer inquiries (particularly those from physicians, patients, and insurance carriers) pertaining to the HCFA reimbursement policy to Sharon Hippler at: HCFA, 7500 Security Boulevard, C4-04-05, Baltimore, MD 21244 or (410) 786-4633.

E. Sponsor Inquiries and Requests for Re-evaluation of Categorization Decisions

The division may discuss the basis for the reimbursement categorization with the study sponsor. A request for re-evaluation of the reimbursement determination must be submitted in writing to FDA as an IDE supplement. Upon receipt of this request, the reviewing division will reconsider the original decision and issue a letter setting forth the basis of its final decision. The appropriate boilerplate letter (H-2 on the LAN) should be used when responding to such requests, and IDE Staff concurrence must be obtained before the letter is issued. After this point, the sponsor must refer any subsequent inquiries regarding the categorization decision to HCFA as FDA's determination may be only one of several factors considered when the reimbursement decision is made and HCFA is the final arbiter of all reimbursement decisions.

F. Updating of the Categorization Decisions

If the circumstances which led to the original categorization determination change (e.g., a PMA is approved for a device similar to one under investigation), the reviewing division will be responsible for reconsidering the categorization designation for all IDEs which may have been affected by this change. Any resulting modifications must be immediately reported to the IDE Staff. The IDE Staff will be responsible for reporting these changes in the categorization designation to both HCFA and the sponsor of the IDE (See boilerplate H-3 on the LAN).

Effective Date

This memorandum is effective immediately.

Philip J. Phillips

Interagency Agreement

Between the Health Care Financing Administration (HCFA) and the Food and Drug Administration (FDA) regarding Medicare coverage of certain investigational medical devices.

I. Purpose

To establish a process by which FDA will assist HCFA to place IDE devices into categories based on the level of risk the device presents to patients. This categorization will be used by HCFA as part of its determination of which devices meet the requirements for Medicare coverage under section 1862(a)(1)(A) of the Social Security Act (the, "reasonable and necessary" clause). To be covered under Medicare, the device must be reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member.

II. Authority

The legal authority to enter into this Agreement is provided in sections 1874 and 1862(a)(1)(A) of the Social Security Act and sections 520(g) and 701(a) of the Federal Food, Drug and Cosmetic Act.

III. Background

In his National Performance Review, Vice President Gore directed the health agencies of the Department of Health and Human Services (HHS) to review their policies and processes to determine which requirements could be reduced or eliminated without lowering health and safety standards. In accordance with this directive, FDA reviewed its current regulatory approval processes and HCFA reviewed its Medicare coverage policies for medical devices that have not received full FDA approval.

The Medicare program has historically interpreted the statutory terms "reasonable and necessary" to mean that a service or medical device must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. For Medicare coverage purposes, the term experimental has been used synonymously with the term investigational. Therefore, an approved Investigational Device Exemption (IDE) application served as an indication that the device was not "reasonable and necessary" within the meaning of the Medicare program. Under this policy, Medicare coverage was denied for devices that require, but have yet to receive, 510(k) clearance and those that have received an IDE but have not received PreMarket Approval (PMA).

There is increasing recognition that there are devices which are refinements of existing technologies or replications of existing technologies by other manufacturers. Many of these devices are placed within the IDE category as a means of gathering the scientific information necessary for FDA to establish the safety and effectiveness of the particular device, even though there is scientific evidence that the type of device can be safe and effective. Arguably, these devices could be viewed as "reasonable and necessary" by Medicare and recognized for payment if it were possible to identify them in the FDA's process.

Accordingly, FDA and HCFA are developing a revised policy to meet the needs of Medicare beneficiaries. The purpose of this effort is to determine if it is feasible to expand. Medicare coverage to include certain medical devices that have not yet received FDA marketing approval/clearance without compromising the safety of medical care provided to Medicare beneficiaries. The intent is to devise ways to:

- assure Medicare beneficiaries greater access to advances in proven medical technology;
- encourage clinical researchers to conduct high quality studies; and,

- clarify Medicare coverage of reasonable and necessary medical services during clinical trials for investigational devices.

IV. Scope of Work and Responsibilities

The Health Care Financing Administration, in conjunction with the Food and Drug Administration, will develop a process to differentiate between novel, first-of-a-kind medical devices and newer generations of proven technologies. New Medicare policies will be established in accordance with the requirements for Federal rule-making under section 553 of the Administrative Procedure Act.

This Interagency Agreement (IA) supports this process under which HCFA will establish a stratified policy for Medicare coverage of certain IDE devices under FDA review. For purposes of assisting HCFA in determining Medicare coverage, the FDA will place all IDEs it approves in one of two categories:

- Category A - Experimental- innovative devices believed to be in class III for which "absolute risk" of the device type has not been established (i.e., initial questions of safety and effectiveness have not been resolved). That is, FDA is unsure whether the device type can be safe and effective.

- Category B - Non-experimental/Investigational - device types believed to be in classes I or II or device types believed to be in class III where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.1

In order to properly categorize device investigations, HCFA and FDA have agreed to employ criteria outlined in the

Attachment. As experience is gained in making categorizations, the criteria may be updated.

For purposes of determining Medicare coverage, medical devices classified under this system as "Category B: Non-experimental/Investigational," could be viewed as "reasonable and necessary" if they also meet all other Medicare coverage requirements. In some cases, HCFA may also wish to conduct a separate assessment of the device to determine medical necessity and appropriateness specifically with respect to Medicare beneficiaries.

In support of this basic agreement HCFA and FDA agree to the following:

- FDA will assign each FDA-approved IDE to one of the two categories listed in the Attachment and notify HCFA of its categorization no less than each calendar quarter, either by electronic means or written communication.

- Medicare coverage of devices under "investigation" is predicated, in part, upon their status with FDA. In the event a sponsor loses its category B categorization or violates relevant IDE requirements necessitating FDA's withdrawal of approval of the IDE, FDA will immediately notify HCFA in order that HCFA may reevaluate the coverage status of the device under Medicare. HCFA will establish specific procedures for the withdrawal of Medicare coverage. These procedures will be described in Medicare regulations.

- FDA-approved IDE study protocols for each clinical study will require that devices be available in a circumscribed number of sites for an approved number of patients. HCFA will provide Medicare coverage and payments in accordance with these limitations and other" protocol requirements (i.e., services provided by certain health care practitioners).

- FDA will assign each IDE an identification code or number which will enable HCFA to establish special

claims processing procedures for Medicare claims associated with the clinical trial. FDA will complete this process for existing IDEs by November 1, 1995.

- FDA will require that the sponsor/manufacturer and clinical-investigators adhere to, pertinent regulations, including obtaining informed consent for all patients participating in the clinical trial.

- FDA will establish a process for the reconsideration of the categorization of IDE devices. As part of this process, FDA will analyze all information submitted by a party in support of a request for reconsideration. HCFA will establish-a process to review requests for reconsideration that are denied by FDA. FDA will provide necessary technical and expert support relating to FDA's categorization of devices to HCFA during the review process. FDA will provide information to HCFA to substantiate its decision on the categorization of each medical device under review.

- Reimbursement under the Medicare program for a device under an approved IDE will be limited to what Medicare would have paid for a comparable approved device.

Note: Under the Food, Drug, and Cosmetic Act, devices are categorized into three classes. Class I devices are the least regulated devices. These are devices that FDA has determined need to be subject only to general controls, such as good manufacturing practice regulations. Class II devices are those which, in addition to general controls, require special controls, such as performance standards or post-market surveillance, to assure safety and effectiveness. Class III devices are - those which cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require Pre-Market Approval (PMA).

V. Period of Agreement

This agreement takes effect upon the signatures of the two parties. The policy will be effective when final regulations are published in the Federal Register, expected to be on or about November 1, 1995. The agreement will continue in effect for an indefinite period.

VI. Modification/Cancellation Provisions

This Interagency Agreement (IA) may be modified at any time by mutual agreement of the patties. It may be canceled if both parties so agree in connection with a review, or if a Federal statute is enacted that materially affects the IA. In the event there is a cancellation of the IA, that cancellation will not be effective for at least 6 months.

VII. Confidentiality of IDE Information

FDA will provide HCFA access to all information in the IDE application for making Medicare coverage and payment determinations, insuring protection against program fraud and abuse, and claims processing. All IDE applications will remain on FDA premises. However, relevant portions of these applications may be duplicated by HCFA, as necessary, for purposes of Medicare coverage determinations.

To the extent that such information is in the possession and control of HCFA, it is subject to the disclosure and withholding rules established by Federal statutes and regulations. Applicable Federal statutes include, but are not limited to, the Freedom of Information Act (5 U.S.C. 552), the Privacy Act (5 U.S.C. 552a), the Social Security Act (42 U.S.C. 1306a), and the Trade Secrets Act (18 U.S.C 1905). Under this agreement, FDA will have a role in ensuring that its data release standards are met, either by reviewing any materials and paperwork to be released by HCFA, or through some other forms of oversight. Moreover, HCFA has no present intention of disclosing, or authorizing the disclosure of, individual/patient or proprietary

information.

VIII. Points of Contact

HCFA: Thomas Ault, Director
Bureau of Policy Development

FDA: D. Bruce Burlington, M.D.
Director, Center for Devices
and Radiological Health

IX. Signatures of Acceptance

8/29/95
Date

_____/S/_____
Bruce C. Vladeck, Administrator
Health Care Financing Administration

9/8/95
Date

_____/S/_____
David A. Kessler, M.D.
Commissioner of Food and Drugs
Food and Drug Administration

Attachment

CRITERIA FOR CATEGORIZATION OF INVESTIGATIONAL DEVICES

Category A: Experimental

1. Class III devices of a type for which no marketing application has been approved through the premarket approval (PMA) process for any indication for use. (For preamendments Class III devices, refer to the criteria under Category B); or

2. Class III devices that would otherwise be in Category B but have undergone significant modification for a new indication or use.

Category B: Non-experimental/Investigational

1. Devices, regardless of the classification, under investigation to establish substantial equivalence to a predicate device, i.e., to establish substantial equivalence to a previously/currently legally marketed device: or

2. Class III devices whose technological characteristics and indications for use are comparable to a PMA-approved device; or

3. Class III devices with technological advances compared to a PMA approved device, i.e., a device with technological changes that represent advances to a device that has already received pre-market approval (generational changes); or

4. Class III devices that are comparable to a PMA-approved device but are under investigation for a new indication for use. For purposes of studying the new indication, no significant modifications to the device were required; or

5. Pre-amendments Class III devices that become the subject of

an IDE after FDA requires premarket approval, i.e., no PMA was submitted or the PMA was denied; or

6. Non-significant risk device investigations for which FDA required the submission of an IDE.

Note: Some investigational devices may exhibit unique characteristics or raise safety concerns that make additional consideration necessary. For these devices, HCFA and FDA will agree on the additional criteria to be used. FDA will then use this criteria to assign the device(s) to a category. As experience is gained in the categorization process, this attachment may be modified.

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CRITERIA FOR CATEGORIZATION OF INVESTIGATIONAL DEVICES

Category A: Experimental

_____ 1) Class III devices of a type for which no marketing application has been approved through the premarket approval (PMA) process for any indication for use. (For pre-amendments Class III devices, refer to the criteria under Category B); or

_____ 2) Class III devices that would otherwise be in Category B but have undergone significant modification for a new indication for use.

Category B: Non-experimental/Investigational

_____ 1) Devices, regardless of the classification, under investigation to establish substantial equivalence to a predicate device, i.e., to establish substantial equivalence to a previously/currently legally marketed device; or

_____ 2) Class III devices whose technological characteristics and indications for use are comparable to a PMA-approved device; or

_____ 3) Class III devices with technological advances compared to a PMA-approved device, i.e., a device with technological changes that represent advances to a device that has already received pre-market approval (generational changes); or

_____ 4) Class III devices that are comparable to a PMA-approved device which are under investigation for a new indication for use. For purposes of studying the new indication, no significant modifications to the device were required; or

_____ 5) Pre-amendments Class III devices that become the subject of an IDE after FDA requires premarket approval, i.e., no PMA

was submitted or the PMA was denied; or

_____ 6) Non-significant risk device investigations for which FDA required the submission of an IDE.

_____

Branch Chief (date)

For Category A determinations only:

_____

IDE Staff concurrence (date)

Below is a list of the HCFA Reimbursements Categorization Determinations for FDA-Approved IDE's:

G780049 B 2
G780054 B 2
G790001 B 2
G790011 B 6
G790012 B 2
G790016 B 1
G790018 B 2
G790022 B 2
G790023 B 2
G790030 B 2
G790033 B 1
G800001 B 2
G800002 B 2
G800004 B 2
G800007 B 1
G800017 B 5
G800020 B 1
G800022 B 2
G800024 B 2
G800035 B 3
G800046 B 1
G800049 B 2
G800055 B 2
G800074 B 2
G800075 B 1
G800077 B 2
G800083 B 4
G800124 B 2
G800129 B 3
G800138 B 2
G800143 B 4
G810003 B 2
G810022 B 2
G810028 B 2
G810065 B 2
G810067 B 4
G810068 B 2
G810076 B 2

G810080 B 1
G810081 B 1
G810083 B 2
G810086 B 1
G810089 B 2
G810102 B 1
G810109 B 2
G810113 B 1
G810115 B 3
G810122 B 2
G810123 B 2
G810127 B 2
G810128 B 2
G810129 B 1
G810134 B 1
G810138 B 2
G810139 B 1
G810149 B 2
G810161 B 2
G810168 B 1
G810171 B 2
G810172 B 2
G810173 B 2
G810178 B 2
G810192 B 2
G810203 B 2
G810216 B 2
G810218 B 2
G820012 B 2
G820019 B 2
G820033 B 1
G820036 B 2
G820046 B 2
G820050 B 2
G820054 B 2
G820057 B 2
G820061 B 3
G820073 B 1
G820076 B 2
G820080 B 1
G820082 B 2

G820094 B 4
G820096 B 2
G820098 B 2
G820115 B 2
G820138 B 2
G820149 B 2
G820157 B 2
G820165 B 2
G820903 B 1
G820904 B 1
G830017 B 4
G830027 B 2
G830044 B 2
G830048 B 2
G830073 B 4
G830092 B 4
G830120 B 2
G830127 B 2
G830134 B 1
G830145 B 2
G830153 B 1
G830154 B 4
G830167 B 2
G830174 B 2
G830187 B 2
G830901 B 1
G830903 B 1
G830907 B 2
G840008 B 1
G840018 B 1
G840028 B 3
G840032 B 1
G840036 B 2
G840069 B 1
G840080 B 2
G840098 B 2
G840099 B 1
G840129 B 1
G840135 B 2
G840137 B 6
G840140 B 2

G840150 B 1
G840174 B 2
G840189 B 2
G840196 B 2
G840201 B 2
G840208 A 1
G850010 B 2
G850012 B 1
G850017 B 1
G850030 B 2
G850040 B 2
G850045 B 1
G850049 B 2
G850071 B 2
G850072 B 1
G850097 B 2
G850098 B 2
G850101 B 3
G850103 B 4
G850117 B 3
G850120 B 2
G850121 B 2
G850134 B 2
G850139 B 2
G850142 B 1
G850158 B 4
G850162 B 2
G850174 B 2
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G850202 B 2
G850206 B 2
G850217 B 2
G850231 B 2
G850233 B 4
G850239 B 2
G860001 B 1
G860010 B 2
G860019 B 4
G860021 B 1
G860026 B 2

G860030 B 4
G860044 B 2
G860055 B 2
G860060 B 2
G860065 B 3
G860066 B 2
G860067 B 2
G860070 B 3
G860075 B 2
G860077 B 2
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G860114 B 2
G860116 B 1
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G860118 B 1
G860132 B 2
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G860141 B 4
G860147 B 4
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G860157 B 1
G860165 B 4
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G860169 B 2
G860170 B 2
G860172 B 2
G860176 B 1
G860182 B 2
G860184 B 4
G860186 B 2
G860189 B 1
G860194 B 2
G860199 B 2
G860200 B 2
G860201 B 1
G860210 B 1
G860225 B 2
G860230 B 4

G870010 B 4
G870013 B 1
G870017 B 1
G870019 B 3
G870030 B 2
G870031 A 1
G870035 B 2
G870036 B 2
G870037 B 2
G870038 B 6
G870040 B 3
G870046 B 2
G870048 B 4
G870049 B 1
G870052 B 1
G870053 B 2
G870055 B 6
G870056 B 6
G870058 B 1
G870060 B 1
G870061 B 6
G870067 B 2
G870069 B 4
G870080 B 2
G870082 B 2
G870091 B 1
G870101 B 4
G870104 B 2
G870109 B 2
G870112 B 1
G870114 B 2
G870120 B 2
G870122 B 6
G870123 B 2
G870129 B 2
G870134 B 6
G870136 B 2
G870142 B 4
G870144 B 4
G870158 B 6
G870161 B 2

G870163 B 2
G870167 B 1
G870174 B 2
G870181 A 2
G870195 B 2
G870200 B 2
G870213 B 2
G870224 B 2
G880001 B 1
G880007 B 3
G880008 B 4
G880018 B 4
G880021 B 2
G880022 B 3
G880026 B 1
G880028 A 1
G880032 B 3
G880040 B 2
G880042 B 1
G880044 B 2
G880045 B 1
G880050 B 6
G880051 B 2
G880063 A 1
G880068 B 2
G880069 B 3
G880076 B 1
G880080 B 2
G880084 B 2
G880100 B 2
G880102 B 1
G880103 B 1
G880104 B 1
G880112 B 3
G880118 B 4
G880122 B 2
G880123 B 6
G880129 B 2
G880131 B 2
G880136 B 6
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G880150 B 2
G880151 A 1G880152 B 2
G880153 B 2
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G880157 B 6
G880159 B 1
G880167 B 2
G880170 B 3
G880174 B 6
G880184 B 2
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G880214 B 4
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